

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

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FORM 10-K  

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(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2023

OR

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

Commission File Number 001-41859

**CARGO Therapeutics, Inc.**

(Exact name of Registrant as specified in its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)  
1900 Alameda Las Pulgas, Suite 350  
San Mateo, California  
(Address of principal executive offices)

84-4080422  
(I.R.S. Employer  
Identification No.)

94403  
(Zip Code)

Registrant's telephone number, including area code: (650) 379-6143

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 \$0.001 per share	CRGX	Nasdaq Global Select Market

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

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

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

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

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

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

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

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

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

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 was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting equity held by non-affiliates as of such date.

The number of shares of Registrant's Common Stock outstanding as of March 13, 2024 was 39,363,052.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive proxy statement relating to the 2024 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements in this Annual Report on Form 10-K, other than statements of historical fact, including, without limitation, statements regarding our strategy, future operations, future operating expenses, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives may be forward-looking statements. The words “aim,” “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “should,” “would” or “will,” and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this report include, but are not limited to, statements about:

- the potential for adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates;
- the timing of achieving our scientific, clinical, manufacturing, regulatory and/or other product development objectives;
- the timing of our planned investigational new drug submissions to the Food and Drug Administration for our product candidates, including CRG-022;
- our expectations regarding the potential market size and size of the potential patient populations for our product candidates and any future product candidates, if approved for commercial use;
- our clinical and regulatory development plans;
- our expectations with regard to the results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies;
- the number, size and design of our planned clinical trials, and what regulatory authorities may require to obtain full marketing approval;
- our plans to research, develop and commercialize our product candidates, including CRG-022 and CRG-023;
- the timing of commencement of future preclinical studies and clinical trials and research and development programs;
- our ability to acquire, discover, develop and advance product candidates into, and successfully complete, clinical trials;
- our ability to obtain designation as a Breakthrough Therapy for one or more of our product candidates;
- a requirement to obtain approval of a companion diagnostic in connection with the approval of any of our product candidates;
- our intentions and our ability to establish collaborations and/or partnerships;
- the discovery of previously unknown or unexpected problems with our product candidates or any future product candidates or with the facilities where such product candidates are or will be manufactured;
- the timing or likelihood of regulatory filings and approvals for our product candidates, including the potential requirement to adopt a Risk Evaluation and Mitigation Strategy;
- our commercialization, marketing and manufacturing, including the buildout of our own manufacturing facility, capabilities and expectations;
- the rate and degree of market acceptance of our product candidates;
- the success of competing products or platform technologies that are or may become available;

- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- our intentions with respect to the commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- the pricing and reimbursement of our product candidates, if approved;
- future agreements with third parties in connection with the commercialization of our product candidates;
- the potential effects of public health crises, such as the COVID-19 pandemic, on our preclinical and clinical programs and business;
- the implementation of our business model and strategic plans for our business and product candidates, including additional indications for which we may pursue;
- our ability to effectively manage our growth, including our ability to attract and retain key scientific and management personnel, and maintain our culture;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected terms of patent protection;
- potential claims relating to our intellectual property and third-party intellectual property;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our future financial performance;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and a smaller reporting company as defined in Rule 12b-2 of the Securities and Exchange Act of 1934, as amended (the Exchange Act);
- developments and projections relating to our competitors and our industry, including competing products;
- our expectations regarding the use of proceeds from our initial public offering and our existing cash and cash equivalents; and
- other risks and uncertainties, including those listed under the caption “Risk Factors” in this Annual Report on Form 10-K.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. 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 report, 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 you are cautioned not to unduly rely upon these statements.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website, Securities and Exchange Commission filings, webcasts, press releases and conference calls. We use these mediums, including our website, to communicate with the public about our company, our business and other issues. It is possible that the information that we make available may be deemed to be material information. We, therefore, encourage investors and others interested in our company to review the information that we make available on our website.

## PART I

### Item 1. Business.

#### Overview

We are a clinical-stage biotechnology company uniquely positioned to advance next generation, potentially curative cell therapies for cancer patients. Our programs, platform technologies, and manufacturing strategy are designed to directly address the limitations of approved chimeric antigen receptor (CAR) T-cell therapies. A CAR is a protein that has been engineered to modify T cells so they can recognize and destroy cancer cells. We believe the limitations of approved therapies include limited durability of effect, safety concerns and unreliable supply. Our lead program, CRG-022, an autologous (derived from a patient's cells) CD22 CAR T-cell product candidate, the underlying CAR of which we exclusively licensed, is being studied by Stanford University (Stanford) in a Phase 1 clinical trial in patients with large B-cell lymphoma (LBCL) whose disease relapsed or was refractory (R/R) to CD19 CAR T-cell therapy. On the basis of the results from the clinical trial, we are evaluating CRG-022 in a potentially pivotal Phase 2 clinical trial in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. We also plan to evaluate CRG-022 in patients at earlier stages of disease, including LBCL and other hematologic malignancies. Beyond our lead program, we are leveraging our proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multiple transgene therapeutic "cargo" designed to enhance CAR T-cell persistence, as well as to help safeguard against tumor resistance and T-cell exhaustion. Our founders are pioneers and world-class experts in CAR T-cell therapy, and our team has significant experience and success developing, manufacturing, launching and commercializing oncology and cell therapy products. We aim to become a fully integrated, leading cell therapy company. Together, we are united in our mission to outsmart cancer and deliver more cures for patients.

Transformative advances have been made by commercially available CAR T-cell therapies; however, resistance mechanisms in hematologic malignancies can limit the strength and quality of T-cell response and contribute to disease progression, including loss or down-regulation of target antigen expression, loss of co-stimulation and limited CAR T-cell persistence. For example, as shown in the ZUMA-1 clinical trial for Yescarta in LBCL patients with two or more prior lines of therapy, approximately 60% of LBCL patients treated with Yescarta had their disease relapse or progress within 24 months. As CD19 CAR T-cell therapies continue to expand into earlier lines of therapy and additional geographies, there is a large growing unmet need for the majority of patients who do not experience a durable response. According to our estimates, we expect by 2030 approximately 7,600 patients annually may need treatment post CD19 CAR T-cell therapy within the United States as well as France, Germany, Italy, Spain and the United Kingdom (EU4/UK).

Our lead program, CRG-022, is a novel autologous CAR T-cell product candidate designed to address resistance mechanisms by targeting CD22, an alternate tumor antigen expressed in most B-cell malignancies. We exclusively licensed the underlying CAR for CRG-022 from the National Cancer Institute (the NCI), for use as an autologous cell therapy in hematology and oncology. Prior to our licensing the underlying CAR from the NCI, Stanford had begun a Phase 1 clinical trial of CRG-022, which has enrolled 41 patients with R/R LBCL, 38 of whom received CRG-022. The results below reflect a data cut-off as of November 4, 2023:

- For all patients treated (n=38), the overall response rate (ORR) was 68% (26 of 38 patients), and the complete response (CR) rate was 53% (20 of 38 patients);
- The November 2023 data cut-off provides a median follow-up of 27.3 months and includes the following new information from Stanford:
  - Since the previous May 3, 2023 data cut-off, one additional patient relapsed after a remission duration of 21 months.
  - At Dose Level 1, which was 1 x 10<sup>6</sup> transduced CRG-022 cells per kg and the dose we are using for our ongoing Phase 2 clinical trial, 73% of patients who achieved a CR maintained the CR for at least 12 months (29 patients were treated at Dose Level 1; 15 achieved a CR, 11 of whom maintained a CR for ≥ 12 months).

- At Dose Level 2, 9 patients were treated, with 5 patients achieving a CR. Four of these 5 patients had maintained a CR for 12 months or longer.
- With a median follow-up of 27.3 months as of the data cut-off, for Dose Level 1, the median OS had not been reached and for Dose Level 2, the median OS was 14.1 months.
- Five patients who died of non-relapse causes were in CR at the time of death; 2 of 5 patients were in Dose Level 1 and 3 of 5 patients were in Dose Level 2.
- Only 1 patient at Dose Level 2 experienced Grade 3 or higher cytokine release syndrome (CRS), which happens when a patient's immune system aggressively responds to an immunotherapy;
- No patients experienced Grade 3 or higher immune effector cell-associated neuropathy (ICANS), which is a neurological toxicity that can occur following immunotherapy; and
- Reliable supply with 95% successful manufacturing rate and median turnaround time of 18 days.

There have been 32 serious adverse events reported from 23 subjects on this study as of the November 4, 2023 data cut-off. There were four reports of Grade 3 sepsis/infection and two reports of cardiac disorders, which included grade 3 ejection fraction decreased and grade 2 heart failure. The largest category of reported SAEs (n = 14 events, 44%) have been hospitalizations for closer monitoring during a second peak of CRS that occurs between Day 11 and Day 14 post-CAR infusion.

In addition, the most common adverse events of Grade 3 or higher during treatment were neutropenia, which occurs when patients have lower-than-normal levels of a type of white blood cell and is especially common among people receiving cancer treatments, that was observed in all treated patients, anemia that was observed in 63% of treated patients, and thrombocytopenia, which occurs when bone marrow does not make enough platelets, that was observed in 63% of treated patients. All of these adverse events are commonly observed in other therapeutics in this class. Three deaths in the trial were deemed by investigators to be possibly related to study drug at the highest dose level, which is not being used in our ongoing Phase 2 clinical trial.

On the basis of these results, Stanford received Breakthrough Therapy Designation from the FDA for the treatment of adult LBCL patients whose disease is R/R after CD19-directed CAR T-cell therapy in connection with Stanford's Investigational New Drug application (IND). We understand that Stanford may pursue additional clinical trials of a similar CAR T-cell therapy to CRG-022 in other B-cell malignancies for research purposes. Our and Stanford's clinical trials have been, and will be, conducted independently from each other, with the exception that Stanford is a clinical trial site for our ongoing Phase 2 clinical trial of CRG-022 in R/R LBCL post CD19 CAR T-cell therapy. In August 2023, we initiated a potentially pivotal multi-center Phase 2 clinical trial to evaluate the safety and efficacy of CRG-022 in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. In this growing patient population with significant unmet need, CRG-022 may provide another option and opportunity to achieve a complete and durable response. We expect interim results from this Phase 2 clinical trial in the first half of 2025. Beyond our initial focus on R/R LBCL post CD19 CAR T-cell therapy, we plan to evaluate CRG-022 in additional indications, including patients with LBCL who are CAR T naïve, as well as B-cell acute lymphocytic leukemia (B-ALL).

We are building upon the development of CRG-022 by leveraging our proprietary platform technologies, including our CD2 platform, to enable the development of multi-specific and multi-functional cancer product candidates designed to improve outcomes and survival by addressing multiple mechanisms of resistance and other unmet needs. Our most advanced preclinical program, CRG-023, incorporates a tri-specific CAR to address either tumor antigen loss (e.g., CD19) or low-density antigen expression, loss of co-stimulation (e.g., CD2/CD58) and lack of T-cell persistence. CRG-023 is designed to target tumor cells with three B-cell antigen targets, CD19, CD20 and CD22. This product candidate also integrates a CD2 co-stimulatory domain into the tri-specific CAR T cell to counter a target-independent mechanism, the downregulation of CD58 (the ligand of the CD2 co-stimulatory receptor), that leads to resistance to CAR T cells and other immune therapies.

The strength and quality of a T-cell response is dependent not only on cognate antigen recognition, but also on co-stimulation, which involves interaction of one or more co-stimulatory receptors on T cells, such as CD2, with their cognate ligands (a molecule that typically interacts with a receptor) expressed on the surface of tumor cells, such as CD58. Tumor cells can escape CAR T-cell destruction by downregulating the expression of ligands for the

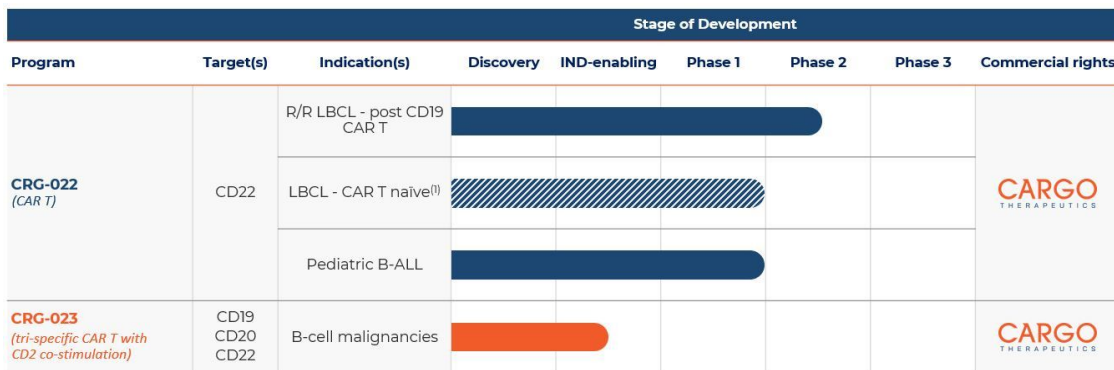
co-stimulatory receptors. Alteration of CD58 expression is associated with poor prognosis in patients with LBCL and leads to lack of response to CD19 CAR T cells. Approximately 25% of LBCL patients that are eligible for CAR T-cell therapy have mutated or absent CD58 and up to 67% have decreased expression of CD58. In addition, a study published in June 2023 demonstrated that aberrant CD58 expression can also occur in a wide range of hematologic malignancies including Hodgkin and non-Hodgkin lymphomas (both B-cell and T-cell), including de novo disease, suggesting a potential utility for our CD2 platform technology to mitigate immune escape in future therapies. Our CD2 platform creates constructs that couple CD2 signaling directly to CAR activation, thereby engaging CD2 signaling even in the presence of tumor cells that have reduced aberrant CD58 expression. We leveraged this platform to uniquely differentiate CRG-023.

A second platform technology, which we refer to as STASH, is designed to enable multiplex engineering of a variety of immune cell types. This platform could enable us to incorporate multiple transgene therapeutic “cargo” designed to enhance CAR T-cell persistence, as well as to help safeguard against tumor resistance and T-cell exhaustion.

Despite the curative potential of cell therapies, we believe these treatments are not readily available to many of the patients who could benefit from them due to manufacturing challenges, supply constraints, unpredictable turnaround time and other logistical challenges. With the goal of addressing these issues, our team developed the intended commercial manufacturing process and analytical control strategy for CRG-022, while demonstrating comparability of the final drug product to that produced by the process used in the Stanford Phase 1 clinical trial. Specifically, our CRG-022 IND included our comprehensive data supporting the comparability of our intended commercial manufacturing process to the process used in the Stanford Phase 1 clinical trial, as well as qualified testing methods for the lentiviral vector and cell product, including a potency assay. We developed the intended commercial process prior to initiating our potentially pivotal Phase 2 clinical trial in order to potentially minimize the need for process or analytical changes post-pivotal clinical trial. In addition, we believe our strategy reduces the need for additional complex comparability studies post-pivotal clinical trial. Our process is designed to be readily transferrable, which we believe positions us to scale capacity if demand increases. The transferability of the process is enabled by the use of a single-cell processing device coupled with automated unit operations and a comparability framework.

**Our programs**

Our initial focus is to treat patients with high unmet need and poor survival outcomes who develop resistance to current guideline recommended cancer therapies. In the future, we aim to treat patients at earlier stages of disease to help prevent resistance from emerging in order to extend the durability of response. The figure below summarizes our pipeline of wholly owned CAR T-cell therapies designed to address key mechanisms of resistance for the treatment of a variety of cancers.



(1) Based on data from the Phase 1 clinical trial conducted by Stanford and pending data from our ongoing Phase 2 clinical trial in R/R LBCL – post CD19 CAR T, we are in discussions with the FDA on the initiation of a Phase 2 program in LBCL – CAR T naïve without completing earlier clinical trials in LBCL – CAR T-naïve patients.



*Our lead program, CRG-022*

CRG-022 is an autologous CAR T-cell product candidate that targets CD22, a B-cell specific antigen that has been reported to be expressed in 81% to 100% of diffuse large B-cell lymphoma (DLBCL) patients. Importantly, CD22 expression is usually retained following loss of CD19 antigen expression in patients who become resistant to CD19 CAR T-cell therapy. Beyond targeting CD22, CRG-022 is also designed to incorporate several key features including its short linker, a single-chain variable fragment (scFv) targeting a membrane-proximal epitope on CD22 and its fully human composition, which, respectively, are designed to improve efficacy by increasing dimerization, minimizing resistance and reducing immunogenicity. Additionally, the CAR incorporates the 4-1BB co-stimulatory domain, which has been shown to improve long-term persistence.

We are initially focused on developing CRG-022 to treat patients with LBCL whose disease is R/R following CD19 CAR T-cell therapy. LBCL is a composite of different subtypes and includes DLBCL, high-grade B-cell lymphomas, primary mediastinal B-cell lymphoma (PMBCL) and grade 3B or transformed follicular lymphoma (FL). LBCL is the most common aggressive lymphoid malignancy in the United States and Europe, accounting for approximately 30% to 40% of all non-Hodgkin lymphomas (NHL), a disease with over 80,000 new diagnoses a year. Many DLBCL patients (approximately 30% to 50%) do not respond to or relapse after initial treatments, and then become eligible for CAR T-cell therapy targeting CD19.

Since 2017, the FDA has approved three autologous CD19 CAR T-cell products for the treatment of LBCL, which generated \$1.3 billion in sales in DLBCL in 2022 in the United States/EU4/UK alone and are projected to grow to \$2.6 billion and \$3.3 billion sales annually by 2026 and 2030, respectively, according to data published by Clarivate Disease and Landscape Forecasting (NHL, CLL) 2023. CD19 CAR T-cell therapies can induce long-term remission in some patients, however, as shown in the ZUMA-1 clinical trial for Yescarta in LBCL patients with two or more prior lines of therapy, approximately 60% of LBCL patients treated with the CD19 CAR T-cell therapy had their disease relapse or progress within 24 months. As more patients receive these therapies, driven by recent approvals in earlier lines of therapy and geographic expansion, the unmet need for those who do not experience a durable response is growing. There is currently no broadly recognized standard of care for patients with LBCL whose disease does not respond to or relapses following treatment with CD19 CAR T-cell therapies. The prognosis for this patient population is poor with a median OS of approximately five to eight months.

To help address the significant unmet need in this patient population, we are developing CRG-022, of which the underlying autologously derived CAR we exclusively licensed from the NCI. This CAR has been included in CD22 CAR T-cell product candidates dosed in more than 120 patients in several clinical trials conducted by Stanford and the NCI. The Stanford Phase 1 clinical trial enrolled 41 patients with LBCL whose disease was R/R to CD19 CAR T-cell therapy, including one patient whose disease was CD19-negative and was CD19 CAR T naïve. The primary endpoints for the Stanford clinical trial were (1) assessing manufacturing feasibility; (2) evaluating the severity of adverse events and dose limiting toxicities (DLT); and (3) establishing the maximum tolerated dose and recommended Phase 2 dose of CRG-022. Secondary endpoints included ORR, progression-free survival and overall survival. One patient withdrew from the clinical trial prior to leukapheresis and two patients did not receive CRG-022 due to an inability to manufacture given limited patient T cells, resulting in a 95% successful manufacturing rate (38 of 40 patients) with a median turnaround time of 18 days. In the 38 LBCL patients who received CRG-022, an ORR and a CR rate of 68% and 53%, respectively, was achieved as of the November 4, 2023 cutoff date. With a median follow-up of 27.3 months, for Dose Level 1, the median OS had not been reached as of the data cut-off. For Dose Level 2, the median OS was 14.1 months. As of the November 4, 2023 cutoff date, at Dose Level 1 (the dose we are using for our ongoing Phase 2 clinical trial), 73% of patients who achieved a CR maintained the CR for at least 12 months (29 patients were treated at Dose Level 1; 15 achieved a CR, 11 of whom maintained a CR for  $\geq$  12 months), which we believe suggests favorable durability. At Dose Level 2, 9 patients were treated with 5 patients achieving a CR. Four of these 5 patients had maintained a CR for 12 months or longer as of the data cut-off.

CRG-022 has been generally well-tolerated as of the cutoff date, with only one patient at Dose Level 2 experiencing Grade 3 or higher CRS and no patients experiencing Grade 3 or higher ICANS. In addition, the most common adverse events of Grade 3 or higher during treatment were neutropenia that was observed in all treated patients, anemia that was observed in 63% of treated patients, and thrombocytopenia that was observed in 63% of treated patients. All of these adverse events are commonly observed in other therapeutics in this class. Three deaths in the trial were deemed by investigators to be possibly related to study drug at the highest dose level. Further, two

dose limiting toxicities were observed at the second dose level, leading to de-escalation back to the first dose level. Given this result, it was determined that the Phase 2 optimal dose was the first dose level of  $1 \times 10^6$  transduced CRG-022 cells per kg. Based on this data, we believe that CRG-022 may provide another option and opportunity to achieve a durable and complete response in the growing post CD19 CAR T-cell therapy patient population.

We received feedback from the FDA regarding the design of our potentially pivotal multi-center Phase 2 clinical trial, which we initiated in August 2023, to evaluate the safety and efficacy of CRG-022 in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. Enrollment in the Phase 2 clinical trial is ongoing and, in September 2023, we dosed the first patient. As of January 8, 2024, we had dosed 9 patients in the Phase 2 clinical trial. We expect to report interim results from this Phase 2 clinical trial in the first half of 2025.

In addition to our initial focus on R/R LBCL, we are also evaluating the development of CRG-022 in additional indications, including LBCL in patients who are CAR T naïve, as well as B-ALL. In a Phase 1 clinical trial conducted by the NCI in children and young adults with R/R B-ALL with CD22 expression, treatment with CD22 CAR T-cell therapy using the same CAR as CRG-022 led to a 70% CR rate.

#### *Our tri-specific program, CRG-023*

Our most advanced preclinical program, CRG-023, incorporates 3 unique CARs, designed to address tumor antigen loss and our CD2 platform technology to address loss of co-stimulatory CD58. CRG-023 is designed to target tumor cells with three B-cell antigen targets, CD19, CD20 and CD22. Leveraging our CD2 platform, CRG-023 integrates a CD2 co-stimulatory domain into one of the CAR designs to counter a target-independent mechanism, the downregulation of CD58 (the ligand of the CD2 co-stimulatory receptor), that leads to resistance to CAR T cells and other immune therapies. CD58 alteration is associated with poor prognosis in LBCL and leads to lack of response to CD19 CAR T cells. Approximately 25% of LBCL patients that are eligible for CAR T-cell therapy have mutated or absent CD58 and up to 67% have decreased expression of CD58. In addition, a study published in June 2023 in *Modern Pathology* demonstrated that aberrant CD58 expression can also occur in a wide range of hematologic malignancies including Hodgkin and non-Hodgkin lymphomas (both B-cell and T-cell), including de novo disease, suggesting a potential utility for our CD2 platform technology in future therapies to mitigate immune escape, which occurs when a tumor mutates to escape the patient's immune system. Our CD2 platform creates constructs that couple CD2 signaling directly to CAR activation, thereby engaging CD2 signaling even in the presence of tumor cells that have reduced or eliminated CD58 expression. We leveraged this platform to uniquely differentiate our CRG-023 program. We are initiating IND-enabling studies with CRG-023.

#### **Our strategy**

Our mission is to outsmart cancer by developing the next generation of transformational CAR T-cell therapies to impact patients worldwide with the aim of becoming a fully integrated, leading cell therapy company. Our strategy to achieve this goal is as follows:

- **Build a next generation CAR T-cell company focused on developing and delivering potentially curative therapies to more patients.** Our programs, platform technologies and manufacturing strategy are designed to address the problems of cancer resistance mechanisms and unreliable supply. We are developing technologies that incorporate multiple transgene therapeutic “cargo” to potentially extend persistence of our CAR T-cell therapy candidates with the goal of achieving durable responses that are curative for more cancer patients. We are also executing a comprehensive manufacturing strategy in an effort to address supply issues and increase availability to patients.
- **Advance CRG-022 through a potentially pivotal Phase 2 clinical trial for the treatment of patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy.** Based on the results from the Phase 1 clinical trial being conducted by Stanford, we believe that CRG-022 has the potential to deliver durable anti-tumor responses in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. In September 2023, we dosed the first patient in a potentially pivotal multi-center Phase 2 clinical trial of CRG-022 in this patient population. We expect to report interim results from this Phase 2 clinical trial in first half of 2025.

- **Expand development of CRG-022 to earlier lines of therapy and additional indications. We believe CRG-022 could also be used to treat patients at earlier stages of disease.** We anticipate evaluating CRG-022 for LBCL patients who are naïve to CD19 CAR T-cell therapy. In addition, a CD22 CAR T-cell therapy using the same CAR as CRG-022 demonstrated positive results in a Phase 1 clinical trial conducted by the NCI in pediatric B-ALL, for which we also plan to evaluate CRG-022.
- **Leverage our intended commercial and readily transferable manufacturing process to help mitigate regulatory hurdles and facilitate predictable and reliable supply for future patients.** We believe reliable and predictable supply remains a challenge for existing CAR T-cell therapies. In an effort to resolve this, we developed what we believe is a commercially suitable manufacturing process that uses an automated and closed platform that is designed to be readily transferrable to multiple manufacturing facilities. Our manufacturing process includes features that we believe are critical to long-term manufacturing success and supply reliability such as lentiviral vector from suspension platform and introduction of a cryopreservation step for the incoming apheresis material. We introduced these process features before the initiation of a potentially pivotal Phase 2 clinical trial with the goal of minimizing the need for complex post-pivotal comparability studies. We believe the ease of transferability of our manufacturing process will facilitate rapid scale out by onboarding new manufacturing sites to increase capacity as commercial demand grows.
- **Continue to leverage our platform technologies to advance additional CAR T-cell programs into clinical development.** We intend to leverage our platform technologies to engineer additional T-cell products with improved design features. These features include targeting cancer cells via multiple tumor antigens, elements designed to enhance CAR T-cell persistence, as well as safeguarding against tumor resistance and T-cell exhaustion. We are initiating IND-enabling studies with CRG-023, our tri-specific program candidate targeting CD19, CD20 and CD22. This construct incorporates our CD2 co-stimulatory platform technology with the goal of counteracting potential tumor resistance that can emerge from loss or downregulation of CD58 expression. We intend to continue to invest in our platform technologies to develop multi-specific and multi-functional cancer therapies to address cancer resistance and other unmet needs.
- **Opportunistically pursue strategic partnerships and collaborations to maximize the value of our pipeline and platform technologies.** We currently have exclusive rights to develop and commercialize our product candidates, and to utilize our platform technologies. In the future, we may enter into other collaborations where we believe there is an opportunity to accelerate the development and commercialization of our product candidates while allowing us to retain meaningful rights in major markets. We may also seek to opportunistically acquire or in-license product candidates or technologies that are synergistic with our cell therapy discovery and development efforts.

#### **CAR T cells – an emerging class of immunotherapy with curative potential**

Chimeric antigen receptor (CAR) T cells are T cells engineered to express synthetic receptors capable of specifically recognizing tumor antigens and activating the T cell. Binding of a CAR to its cognate antigen results in stimulation of intracellular signals and activation of T cell activity. There have been six engineered T-cell therapies approved by the FDA for the treatment of cancer. Each of these therapies has been able to deliver therapeutic benefit to patients who have exhausted all other treatment options, and for some patients, these benefits can extend for years.

However, the number of cancers with effective CAR T-cell therapies is limited and the total number of patients who have received these therapies represents only a small fraction of potentially eligible cancer patients. Today, five years after CAR T cells were first approved to treat non-Hodgkin's lymphoma (NHL) and acute lymphocytic leukemia (ALL), over 40,000 U.S. patients may be eligible to be treated by CD19 CAR T-cell therapies, but fewer than 3,800 patients are expected to receive such treatment in 2023. Some patients are deemed ineligible to or do not receive these therapies due to associated toxicity risk, underlying comorbidities, the time needed to manufacture treatment or lack of access to specialized treatment centers. In patients who do manage to receive treatment, not all patients who are treated achieve durable results. For example, as shown in the ZUMA-1 clinical trial for Yescarta in LBCL patients with two or more prior lines of therapy, approximately 60% of LBCL patients treated with the CD19 CAR T-cell therapy had their disease relapse or progress within 24 months.

### **Barriers that limit the impact of approved CAR T-cell therapies**

There are a number of barriers that limit the impact of existing CAR T-cell therapies including:

- *Target-based resistance.* A frequent cause of resistance to CD19 CAR T-cell therapies in patients with B-ALL and LBCL, is the low level of expression of CD19 or the loss of CD19 antigenicity on tumor cells. There are a number of mechanisms that can lead to loss of CD19 antigenicity, such as mutations, splicing variations, antigen glycosylation and antigen-masking, but the end result is the same: the lack of CD19 antigenicity allows tumor cells to escape targeting by CD19 CAR T cells.
- *Non-target-based resistance.* The strength and quality of a T-cell response is dependent not only on cognate antigen recognition, but also co-stimulation. Tumors evolve to escape CAR T-cell destruction through the downregulation of cognate ligands for co-stimulatory signaling molecules. For example, CD58 is the ligand of the CD2 co-stimulatory receptor. Approximately 25% of LBCL patients who are eligible for CAR T-cell therapy have mutated or absent CD58 and up to 67% have decreased expression of CD58. In addition, a study published in June 2023 demonstrated that aberrant CD58 expression can also occur in a wide range of hematologic malignancies including Hodgkin and non-Hodgkin lymphomas(both B-cell and T-cell), including de novo disease. CD58 alteration and corresponding lack of CD2-mediated co-stimulation are associated with poor prognosis in LBCL and lead to decreased progression free survival (PFS) benefit to CD19 CAR T cells.
- *Immunogenicity of CAR constructs.* The majority of approved CAR T-cell therapies incorporate the scFv portion of murine antibodies as the antigen-recognition domain. These domains elicit both humoral and cellular immune responses in patients, which can lead to increased clearance of therapeutic CAR T cells, limiting cell expansion and persistence. This anti-murine immune response increases the likelihood of tumor relapse and can lower the efficacy of CART cells upon reinfusion.
- *Manufacturing challenges with autologous CAR T-cell therapies.* Autologous CAR T-cell therapies require one manufacturing batch per patient which creates unique supply, capacity and logistical challenges. Manufacturing capacity of the approved CAR T-cell products has struggled to meet the demand for these therapies, while also meeting the need for maintaining rapid turn-around-time. We anticipate that this issue will persist as more patients become candidates for CAR T-cell therapy and more complex CAR T cells containing multiple genetic constructs advance into clinical development.

### **Our solution: next generation of potential CAR T-cell therapies**

We are developing a portfolio of product candidates designed to expand the number of patients that can benefit from CAR T-cell therapies by addressing several of the limitations of currently approved CAR T-cell therapies. Our solution includes:

- *Directing CAR T cells toward alternate targets.* Therapies that target single tumor antigens, such as CD19, can be rendered ineffective by genetic or non-genetic changes that diminish the expression of these targets. Our most advanced product candidate, CRG-022, is designed to address an alternate target, CD22, that is nearly always expressed on cancerous B cells, to kill B-cell tumors, including those that have become resistant to CD19-based therapies. We are also developing multi-specific CAR T-cell product candidates, starting with CRG-023, that are designed to recognize tumors that express any of the CD19, CD20 and CD22 antigens, thereby limiting potential antigen loss as a mechanism of resistance.
- *Addressing common mechanism of non-target-based resistance.* In addition to antigen downregulation or loss, resistance to immune therapies, including CAR T cells, can develop through the loss of co-stimulatory signaling, such as tumor cells down regulating CD58 expression. Because these mechanisms are not antigen-specific, loss of co-stimulation can lead to broad suppression of immune therapies. We are working to address loss of co-stimulatory ligands such as CD58, by creating CAR T cells that can induce CD2 co-stimulatory signaling by a tumor antigen irrespective of potential CD58 downregulation or loss on tumor cells.
- *Using fully-human binders to reduce anti-CAR immunogenicity.* Our CAR T product candidates are all constructed with human binders, thereby reducing the risk for anti-CAR immune responses.

- *Implementing robust manufacturing processes.* Our team is applying its extensive experience in the field in an effort to implement manufacturing processes that are highly reliable and readily transferrable to expand capacity, reduce turnaround time and minimize costs of goods. While we are confident in our team's ability to address these manufacturing challenges, these are complex processes and there could be delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners. Further, while we believe it is more cost-efficient to outsource this manufacturing, it is possible that relying on third parties could result in increased costs that could delay, prevent or impair our commercialization efforts. We have also licensed and further developed technologies specifically designed towards the manufacturing and purification of CAR T cells containing multiple genetic inserts delivered by multiple vectors.

## **Our programs and platform technologies**

### ***CRG-022, an autologous CD22 CAR T-cell product candidate***

We are developing CRG-022, an autologous CD22 CAR T-cell therapy, to be a safe, effective and durable therapy with a manufacturing process designed to increase availability by providing consistent and reliable supply. CRG-022 is manufactured using a novel CAR designed to address resistance mechanisms by targeting CD22, an alternate antigen that is expressed in a vast majority of B-cell malignancies. Our initial focus is on developing CRG-022 for the treatment of patients whose disease is R/R to CD19 CAR T-cell therapies. In September 2023, we dosed the first patient in a potentially pivotal multi-center Phase 2 clinical trial to evaluate the safety and efficacy of CRG-022 in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. As of January 8, 2024, we had dosed 9 patients in the Phase 2 clinical trial. We expect to report interim results from this Phase 2 clinical trial in the first half of 2025.

#### *LBCL disease background*

Non-Hodgkin lymphoma (NHL) is the most common hematologic malignancy in adults accounting for a projected 80,550 cases and 4.1% of all new cancer cases in 2023 in the United States. An estimated 20,180 people in the United States will die from this disease in 2023 accounting for 3.3% of all cancer-related deaths. The majority of NHL cases are of B-cell origin and can be further subdivided into aggressive and indolent lymphomas, each associated with different clinical outcomes and prognoses. LBCLs encompass aggressive subtypes including diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphomas, primary mediastinal B-cell lymphoma (PMBCL) and grade 3B or transformed follicular lymphoma (FL).

#### *Current treatment options*

First-line treatment regimens for LBCL include CD20-targeted monoclonal antibodies and anthracycline-containing chemotherapy regimens administered in six to eight cycles. Many DLBCL patients (approximately 30% to 50%) do not respond to or relapse after initial treatments, and then become eligible for CAR T-cell therapy targeting CD19. For decades, the standard approach to treat patients with R/R disease had been salvage chemotherapy followed by high dose platinum-based therapy and autologous stem cell transplant (ASCT). However, this treatment is associated with significant toxicities and approximately half of patients are considered not suitable due to age or other comorbidities. Of the remaining patients considered eligible for ASCT, an additional 50% to 60% do not receive ASCT due to their disease showing no sensitivity to salvage chemotherapy.

Over the past six years, FDA has approved three autologous CD19 CAR T-cell products for the treatment of LBCL. These are axicabtagene ciloleucel (marketed as Yescarta by Kite/Gilead); tisagenlecleucel (marketed as Kymriah by Novartis); and lisocabtagene maraleucel (marketed as Breyanzi by BMS). These therapies have shown objective response rates (ORRs) of 50% to 73% in LBCL patients who have received two or more prior lines of therapy. More recently, Yescarta and Breyanzi have been approved for use in adult patients with LBCL that is refractory to first-line chemoimmuno therapy or relapses within 12 months. Breyanzi has also been approved for use in adult patients with LBCL whose disease is R/R to first-line chemoimmuno therapy and are not eligible for ASCT due to comorbidities or age. These three approved products generated \$1.3 billion of global sales in DLBCL in 2022 in the United States/EU4/UK alone and are projected to generate grow to \$2.6 billion and \$3.3 billion global sales

annually by 2026 and 2030, respectively, according to data published by Clarivate Disease and Landscape Forecasting™ (NHL, CLL) 2023.

While CD19 CAR T cells can induce long-term remissions in some patients, many patients who receive CD19 CAR T-cell therapies experience disease relapse. For example, and as depicted in the figure below, in the ZUMA-1 clinical trial conducted by Kite in LBCL patients with two or more prior lines of therapy, 61% and 68% of patients who received conditioning chemotherapy followed by Yescarta ultimately experience disease progression or death at two years and five years, respectively. As more patients receive these therapies, driven by recent approvals in earlier lines of therapy and geographic expansion, the unmet need for those who do not experience a durable response is growing. Translational studies have shown that CD19 antigen loss or downregulation occurs in about 30% to 60% of cases.

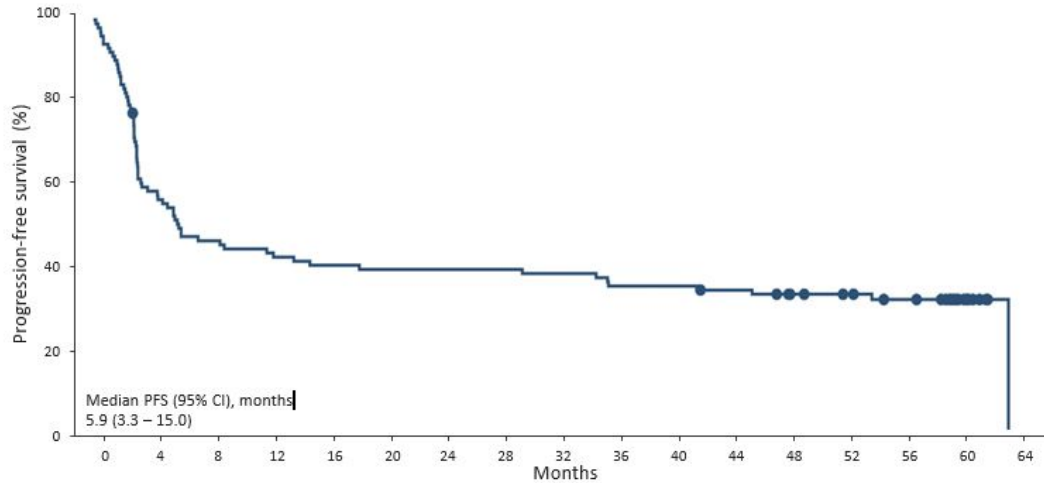


Figure 1. As seen in the Phase 2 clinical trial (ZUMA-1) of Yescarta, approximately 60% percent of patients were observed to not obtain a long-term benefit from CD19 CAR T-cell therapy

There is currently no standard of care for patients with LBCL whose disease does not respond to or relapses following treatment with CD19 CAR T-cell therapies. Treatments with radiotherapy, immunotherapies, targeted therapies and chemotherapy have failed to deliver meaningful improvements in the majority of these patients. Based on third-party studies on patient registries or real-world outcomes, the median OS for patients with aggressive B-NHL post CD19-directed CAR T failure is approximately five to eight months.

*Rationale for targeting CD22*

CD22 is a B-cell antigen expressed independently of CD19 on benign and malignant B cells. CD22 has been reported to be expressed in 81% to 100% of DLBCL patients and 96% to 100% of B-ALL patients. Importantly, CD22 expression is usually retained following loss of CD19 expression in patients who become resistant to CD19 CAR T-cell therapy. As a result, we believe CD22 is an attractive target for a CAR T-cell therapy for patients with B-cell malignancies, including those patients whose disease has relapsed or become refractory to CD19-targeted therapies.

*Key features of CRG-022*

Our lead program, CRG-022, was made using a CAR designed to optimize its potential to deliver antitumor activity against CD22 expressing cells. Key characteristics of CRG-022 include:

*Membrane proximal binding*

CD22 is a protein expressed on the surface of B cells that has an extracellular domain comprised of seven immunoglobulin domains and twelve putative N-linked glycosylation sites. Antibodies have been developed against CD22 and at least three anti-CD22 product candidates have been tested in patients with B-cell malignancies. However, these three antibodies all target the N-terminal domain of CD22, a region of CD22 that may not be ideal for CAR T-cell activation. For example, a third-party study using mesothelin-targeting antigen-binding domains found that membrane-proximal binding led to improved CAR T signaling, potentially because the membrane distal regions interact with other extracellular elements and also because targeting antigen regions close to the membrane increases the likelihood that intracellular co-stimulatory domains will be brought into close proximity.

The gene encoding CD22 contains 15 exons and third-party studies have found multiple splice variants of the CD22 mRNA transcript that encode alternative forms of the protein. CD22-targeted drugs may fail to bind to certain splice variants lacking their targeted epitope. Splice variants for CD19 represent a common mechanism that leads to resistance to CD19 CAR T-cell therapy. Similarly, splice variants of CD22 have been reported in pediatric B-ALL patients treated with a CD22 CAR created by researchers at the University of Pennsylvania.

CRG-022 was made using a CAR that incorporates the antigen-binding domain from an antibody known as m971. This antibody has been shown to bind to the membrane proximal domains of CD22, potentially improving its ability to activate CAR signaling and reducing the potential for splice variants involving the more distal domains, which can lead to resistance.

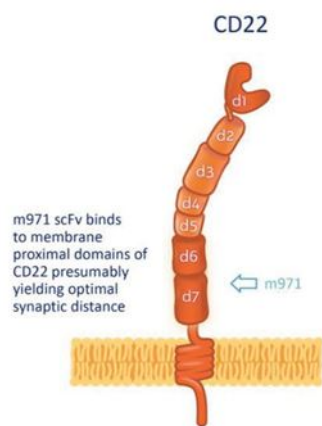


Figure 2. The m971 antigen-binding domain incorporated into the CD22 CAR binds to a membrane proximal domain of CD22

*Short linker*

The CD22 CAR incorporates a synthetic version of the m971 antibody – commonly referred to as a single chain variable fragment (“scFv”)—comprising a truncated polypeptide having both antigen-binding domains of the antibody connected by a flexible peptide linker. The length and sequence of this linker can affect several key performance aspects of CARs, including their expression, oligomeric state, affinity, stability and in vivo activity. The linker used in the CD22 scFv binder in CRG-022 has a short length, a characteristic that has been shown to increase dimerization, which can improve efficacy. By contrast, a CD22 CAR with the same binding domains but a longer linker created by researchers at the University of Pennsylvania was found to have reduced activity both in vitro and in two clinical trials. From two trials in six children and three adults whose disease was R/RCD22+ B-cell ALL, the complete remission

rate was 50% (four out of eight evaluable patients) and of the four patients who achieved or remained in CR, all four progressed with CD22+ disease.

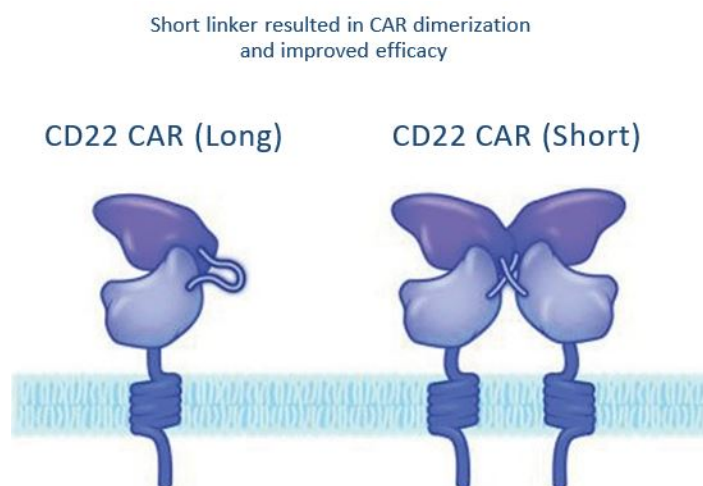


Figure 3. Incorporation of a short linker resulted in increased activity of the CD22 CAR used to create CRG-022

#### *4-1BB co-stimulatory domain*

Binding of the extracellular domain of CARs to cells expressing their corresponding ligands results in activation of T cells through the combined function of intracellular co-stimulatory domains and activation domains. Approved CAR T-cell therapies incorporate co-stimulatory domains from CD28 or from 4-1BB and an activation domain from CD3. It has been shown in a third-party study that the choice of co-stimulatory domain influences the persistence and memory phenotype of CAR T cells. The inclusion of a 4-1BB co-stimulatory domain has been associated with reduced frequencies of serious adverse events and improved clinical outcomes in tumor models. The CD22 CAR used to create CRG-022 contains a 4-1BB co-stimulatory domain.

#### *Fully human antigen-binding domain*

The CD22 CAR used to create CRG-022 contains an antigen-binding domain that is a fully human sequence, which we believe reduces the risk of development of anti-CAR antibodies and T-cell-mediated rejection. Patients treated with CD19 CAR T-cell therapies derived from murine sequences can develop antibodies or T-cell mediated immune responses to the CAR, which may lower persistence of CAR T cells and increase the chances of relapse of the disease. Retreatment of patients with murine-sequence-derived CAR T cells has been shown to primarily result in responses that increase the chance of relapse. A third-party retrospective analysis conducted by researchers at Fred Hutchinson Cancer Research Center evaluated the efficacy of a second infusion of CD19 CAR T cells in 44 patients with R/R B-cell malignancies. A CR rate of 22% in CLL patients, 19% in NHL patients and 21% in ALL patients with median duration of response of 33, 6 and 4 months, respectively was observed. This result was potentially due to host immune rejection after the initial treatment with transgenic T cells. By contrast, retreatment of patients with R/R B-ALL who had received prior CD19 CAR T-cell therapy that failed and used a humanized CD19 CAR T-cell product candidate as a second CAR T treatment, led to a 64% overall response rate at one month with durable remissions. Published data has confirmed that fully human CARs have antitumor activity and tolerability profiles that are similar, if not superior, to those containing murine sequences and may address one mechanism of resistance to CAR T-cell therapy.

#### *Phase 1 Clinical Trial Results for our CRG-022 Program*

As described below, CRG-022 or CD22 CAR T-cell therapy using the CRG-022 CAR has been studied in one Phase 1 clinical trial and continues to be studied in two ongoing Phase 1 clinical trials. In addition, in September 2023, we dosed the first patient in a potentially pivotal multi-center Phase 2 clinical trial to evaluate the safety and efficacy of CRG-022 in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. We licensed the technology



underlying the CD22 CAR used in CRG-022 from the NCI. CRG-022 was produced at Stanford for the Phase 1 clinical trials. We have made additional process and analytical improvements to the Stanford process to create the intended commercial manufacturing process for CRG-022 in an effort to improve manufacturing yields and efficiency. These improvements are reflected in the intended commercial process being used to produce CRG-022 in our potentially pivotal Phase 2 clinical trial. We have performed comparability analyses of CRG-022 produced with our intended commercial process to that produced by the process used in the Stanford Phase 1 clinical trial and concluded that the two are comparable. Moreover, our CRG-022 IND included our comprehensive package to establish the comparability of our CRG-022 produced using the intended commercial process to the CRG-022 produced using the process used for the Stanford Phase 1 clinical trials. We cannot assure you that the FDA will agree with our claim of comparability and the sufficiency of the data to support it, or agree with our ability to reference the preclinical, manufacturing or clinical data generated by the Stanford clinical trial even if we receive a right of reference from Stanford. If the FDA disagrees, there may be limitations on the inclusion of Phase 1 clinical trial data in the product label.

*Phase 1 interim clinical trial results in adults with CD19 CAR T R/R LBCL*

An open-label Phase 1 clinical trial of CRG-022 is being conducted by Stanford enrolled 41 adult patients with CD19 CAR T R/R LBCL. Patients had received an average of four lines of prior therapy including CD19 CAR T-cell therapy for all but one patient whose disease was CD19-negative and was CD19 CAR T naïve. One patient withdrew prior to leukapheresis and two patients did not receive CRG-022 due to an inability to manufacture given limited patient T cells, resulting in a 95% successful manufacturing rate (38 of 40 patients). As of the November 4, 2023 cutoff date, 38 patients had been treated with CRG-022 in this Phase 1 clinical trial.

Patients underwent conditioning chemotherapy with fludarabine and cyclophosphamide before receiving one of the two different doses of CAR T cells (DL1 [1 x 10<sup>6</sup> CD22 CAR+ cells/kg] and DL2 [3 x 10<sup>6</sup> CD22 CAR+ cells/kg]). As shown in the figure below, as of the November 4, 2023, cutoff date, the ORR was 68% and the CR rate was 53%. There was no clear dose-dependence of the ORR or CR rate.

LBCL	DL1 (n=29)	DL2 (n=9)	Total (n=38)
Median follow up, months [range]	27.3 [12.0 – 48.9]	39.8 [35.1 – 43.9]	28.9 [12.0 – 48.9]
Overall Response Rate (ORR)*, n (%)	19 (66%)	7 (78%)	26 (68%)
CR rate	15 (52%)	5 (56%)	20 (53%)
12-mon duration of CR <sup>1</sup>	11/15 (73%)	4/5 (80%)	15/20 (75%)
Median OS, months [95% CI]	NR (8.4 – NR)	14.1 (1.2 – NR)	14.1 (8.4 – NR)

Source: Stanford Phase 1 data presentation at ASH Investigator meeting; Yi-Jiun Su, et al. ASH 2023

Figure 4. ORR and CR observed in Phase 1 clinical trial with CRG-022 as of November 4, 2023

Additionally, as of the cutoff date and as depicted in the graphs below, the overall rate of progression free survival (PFS) at 6 months was 47% and median PFS was 3.0 months (95% CI 1.7-28.7). The median survival in this clinical trial was 14.1 months in the overall population.

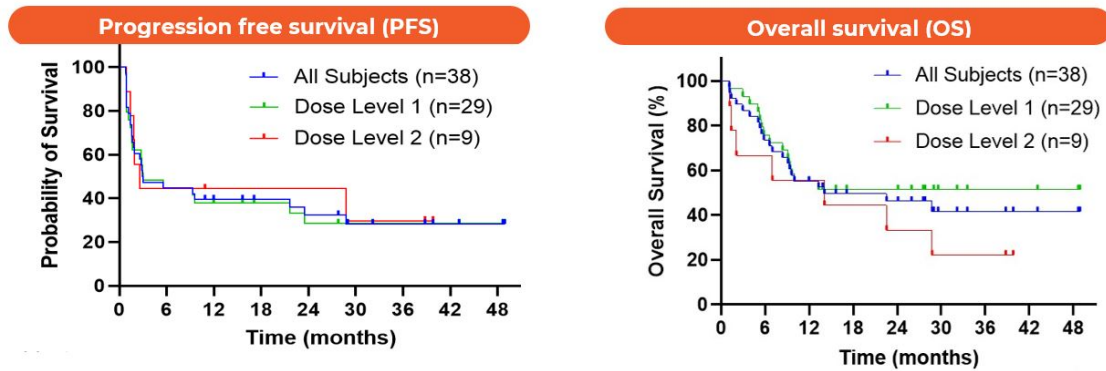


Figure 5. PFS and OS of LBCL patients treated with CRG-022 as of November 4, 2023

Patients treated with CRG-022 experienced an immune toxicity referred to as CRS. CRS is a systemic inflammatory response caused by cytokines released by infused CAR T cells that in severe cases can lead to widespread reversible organ dysfunction and death. The majority of patients treated with CRG-022 had mild to moderate CRS, reported as Grades 1 or 2. Only one patient at DL2 experienced Grade 3 CRS. One patient treated with CRG-022 at DL2 had Grade 2 CRS and developed septicemia, deemed possibly related to CRG-022, which led to multi-organ failure and death due to sepsis on Day 40. Two additional patients at DL2 developed treatment-related MDS/AML without evidence of LBCL relapse at 11- and 28-months post infusion. One patient at DL1 experienced unrelated heart failure and a second patient treated at DL1 died due to unknown causes after being lost to follow-up at six months post CRG-022 infusion.

A second type of toxicity associated with CAR T-cell therapies is ICANS. In the Phase 1 clinical trial, 13% of patients experienced ICANS of Grades 1 or 2 severity. There were no reports of patients with ICANS of Grades 3 or above. We believe the lack of reports of serious grade ICANS could potentially be attributable to the differential expression of CD19 and CD22 on cells within the central nervous system. CD19 is expressed on mural cells which are part of the neurovascular unit surrounding endothelial cells and which are critical for maintaining the integrity of the blood brain barrier. In contrast, researchers have shown that CD22 is not expressed on neurovascular cells, such as mural cells, endothelial cells or neurovascular progenitors.

Parameter	DLBCL DL1 (N = 29)	DLBCL DL2 (N = 9)	Total N=38
<b>Cytokine Release Syndrome, n (%)</b>			
None	2 (7%)	0 (0%)	2 (5%)
Grade 1	13 (45%)	1 (11%)	14 (37%)
Grade 2	14 (48%)	7 (78%)	21 (55%)
Grade ≥3	0 (0%)	1 (11%)	1 (3%)
<b>Neurologic Events / ICANS, n (%)</b>			
None	26 (90%)	7 (78%)	33 (87%)
Grade 1	2 (7%)	1 (11%)	3 (8%)
Grade 2	1 (3%)	1 (11%)	2 (5%)
Grade ≥3	0 (0%)	0 (0%)	0 (0%)

Figure 6. CRS and ICANS observed in Phase 1 clinical trial with CRG-022 as of November 4, 2023  
Source: Stanford Phase 1 data analysis shared at ASH 2023 Investigator meeting

Additionally, 18% of patients (7% of DL1 and 33% of DL2) also developed clinical and laboratory abnormalities consistent with hemophagocytic lymphohistiocytosis (HLH), a condition involving excessive activation of histiocytes and lymphocytes resulting in a hyperinflammatory syndrome requiring prolonged hospitalization or re-admission for medical monitoring or treatment. HLH is recognized as a distinct toxicity associated with CAR T-cell therapies, and it has been observed in approximately 15% of patients treated with CD19 CAR T cells. More recently, a consensus

grading system and management guidelines that include the administration of steroids and anakinra have been developed. This toxicity is now called immune effect or cell HLH-like syndrome (IEC-HS). IEC-HS was higher in patients who received the highest dose (DL2) of CRG-022 without any meaningful increase in efficacy which prompted the selection of DL1 for the expansion phase of this clinical trial.

There have been 32 serious adverse events reported from 23 subjects on this study. There were four reports of Grade 3 sepsis/infection and two reports of cardiac disorders, which included grade 3 ejection fraction decreased and grade 2 heart failure. The largest category of reported SAEs (n = 14 events, 44%) have been hospitalizations for closer monitoring during a second peak of CRS that occurs between Day 11 and Day 14 post-CAR infusion.

In addition, the most common adverse events of Grade 3 or higher during treatment were neutropenia that was observed in all treated patients, anemia that was observed in 63% of treated patients, and thrombocytopenia that was observed in 63% of treated patients. All of these adverse events are commonly observed in other therapeutics in this class. Three deaths in the trial were deemed by investigators to be possibly related to study drug at the highest dose level, which is not being used in our ongoing Phase 2 clinical trial.

*Phase 1 clinical trial of CRG-022 in pediatric and adolescent/young adult patients with R/R B-ALL at Stanford*

A Phase 1 clinical trial of CRG-022 was initiated by researchers at Stanford in pediatric and adolescent/young adult patients with R/R B-ALL or LBCL. As of June 26, 2022, ten pediatric patients and nine adult patients with B-ALL had been enrolled and 16 have been treated. At Day 28, four achieved CR. One pediatric patient developed Grade 3 CRS, carHLH and prolonged neutropenia. This patient developed sepsis, seizure and died on Day 60 of multi organ failure. The eight adult patients treated in this clinical trial all achieved a complete response with five patients achieving MRD-negativity. The median duration of response, either until relapse or next therapy, was 105 days in adult patients, 47.5 days in pediatric patients, and 74 days overall. Twelve patients relapsed after treatment with CRG-022 and overall survival at one year was 50%.

*Phase 1 clinical trial of CD22 CAR T-cell therapy including the CRG-022 CAR in pediatric and adolescent/young adult patients with R/R B-ALL at the NCI*

A single-center Phase 1 clinical trial of a CD22 CAR T-cell therapy using the same CAR as CRG-022 in patients with CD22 positive B-ALL is being conducted at the NCI in children and young adult patients (up to age 30). This clinical trial used a 3 + 3 dose-escalation design with a large expansion cohort and enrolled 73 patients as of April 2019, of which 88% had received CD19-targeted therapy (e.g., CD19 CAR, blinatumomab or both), 67% hematopoietic stem cell transplantation and 24% inotuzumab ozogamicin (a CD22-directed antibody-drug conjugate). The results from 58 patients with highly refractory disease were published in the Journal of Clinical Oncology in 2020. The CR rate was 70% with 88% of responders achieving minimal residual disease negative status. Cytokine release syndrome occurred in 82% of participants but was largely limited to lower grade (i.e., grade 1/2) events (90%). Neurotoxicity occurred in 33% of participants and was severe (i.e., grade  $\geq 3$ ) in 2%. Hemophagocytic lymphohistiocytosis-like manifestations were seen in 32.8% of participants which prompted the use of anakinra.

*Our ongoing potentially pivotal Phase2 clinical trial in LBCL*

In September 2023, we dosed the first patient in a potentially pivotal multi-center Phase 2 clinical trial to evaluate the safety and efficacy of CRG-022 in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. This clinical trial is enrolling patients whose disease is refractory to or has relapsed subsequent to CD19 CAR T-cell therapy. In addition, this clinical trial includes a separate cohort of patients who have received two prior lines of therapy with one of these lines of therapy including a bispecific T cell engager (TCE). The primary objective of this clinical trial is the ORR as determined by a blinded independent review committee. This clinical trial is anticipated to enroll up to 123 patients and dose approximately 101 patients. As of January 8, 2024, we had dosed 9 patients in the Phase 2 clinical trial. We expect to report interim results from this Phase 2 clinical trial in the first half of 2025.

Following fludarabine/cyclophosphamide conditioning, patients will be dosed with  $1 \times 10^6$  viable CAR+ cells/kg, the same dose as the DL1 dose administered in the Stanford Phase 1 clinical trial in LBCL. Initial response assessment is planned for Day 28 with subsequent assessments at Day 90 and then every three months.

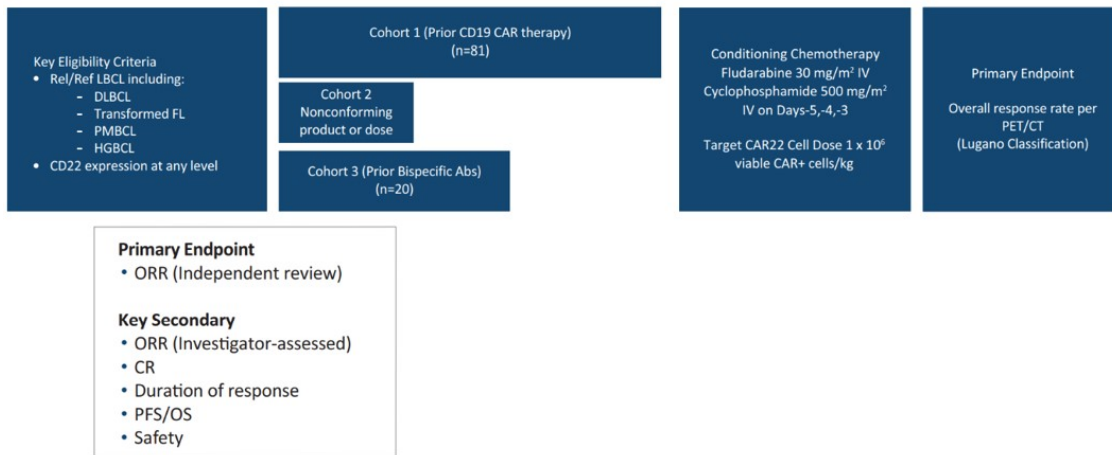


Figure 7. Design of our potentially pivotal Phase 2 clinical trial of CRG-022

**Establishment of a commercial manufacturing process for CRG-022**

CRG-022 is an autologous CAR T-cell product generated from a patient’s own T cells that have been obtained by leukapheresis (a process for patient immune cell collection) and shipped to a manufacturing facility. At the manufacturing facility, CRG-022 is generated, cryopreserved and then shipped back to the treating clinic to be infused into the patient. The manufacturing process for CRG-022 builds upon the process used to manufacture CRG-022 used by Stanford, with the addition of several improvements that we proactively identified as necessary for reliability of long-term supply and that we believe are best implemented prior to initiating a pivotal clinical trial of CRG-022. We believe our manufacturing strategy is designed to directly address some of the key known challenges that cell therapy manufacturers have faced. We are seeking to achieve this by: (1) introducing process design features that enable the process to be rapidly transferable, (2) implementing key process and method changes prior to the start of our potentially pivotal Phase 2 clinical trial, which we believe could reduce the need for changes post-pivotal, (3) automating and closing the process and (4) developing a plan to introduce multiple manufacturing sites for pivotal supply.

Based on the experience of our team in developing and launching cell therapies, we believe that these changes, in addition to being of practical benefit, will also help address critical issues such as supply capacity and cost of goods.

- *Reliable supply.* We have successfully transferred the Stanford manufacturing process to our internal technical development lab, made appropriate process changes and transferred our intended commercial manufacturing process for our potentially pivotal Phase 2 clinical trial to contract development manufacturing organizations (CDMOs). We have identified additional CDMO capacity to help ensure redundancy of supply and increase available capacity in anticipation of commercialization. As an additional focus on our supply chain, we have secured a reliable source of lentiviral vector produced using a suspension-based platform through a collaboration with a CDMO.
- *Cost of goods.* We have automated a number of steps in the manufacturing process to increase throughput and reliability while minimizing costs. For example, we have changed from manual to automated filling as part of the intended commercial manufacturing process. In addition, we have introduced the ability to cryopreserve the starting apheresis material which enables more efficient use of our manufacturing slots and flexible supply chain strategy that can serve patients in wider geographic areas. We addressed the supply of critical reagents required, such as the lentivirus vector that is used to insert the gene for the CD22 CAR into T cells. We transitioned the design and production of the lentivirus vector used by Stanford to one that is more suitable for commercial applications while still delivering the same CD22 CAR and demonstrating analytical comparability to CRG-022 produced at Stanford.

- *Predictable patient experience.* We believe CRG-022 has the potential to deliver life-changing benefits to cancer patients whose disease has failed to respond to prior therapies; however, similar to other autologous cell therapies, a significant amount of time is required to manufacture this autologous CAR T-cell product. The turnaround time encompasses every step from apheresis of the starting cells from the patients, shipping, introduction of the CAR construct, cell expansion, harvesting, final filling and quality control before a product can be released and shipped back to the treating clinic. We believe the process and operational improvements we have implemented will provide greater control of the manufacturing turn-around-time.
- *Regulatory strategy considerations.* We benefit from the experience of pioneering CAR T-cell products to help pave the way through the regulatory process and to identify critical steps with the potential to stall the development of CRG-022. We have, for example, implemented our intended commercial manufacturing process and analytics prior to initialization of our potentially pivotal Phase 2 clinical trial in an attempt to reduce the need to introduce further changes moving from clinical to commercial production. We are utilizing current regulatory guidance to design comparability strategies to manage life cycle changes. We implemented key requirements of the control system, before the start of the potentially pivotal Phase 2 clinical trial, for example by establishing a suitable potency assay and qualifying all release methods.

Our manufacturing approach aims to establish processes that are highly reliable and consistent and that can readily be transferred to commercial cell therapy manufacturing. We believe that this will help ensure that our therapy candidates, if approved, can be generated for all patients that need them. We believe our strategy to focus on these steps prior to initiating our potentially pivotal Phase 2 clinical trial will both simplify later efforts to establish comparability across manufacturing sites and increase our potential to rapidly expand our manufacturing network as dictated by demand.

#### ***Our CD2 co-stimulation platform technology and CRG-023, a tri-specific CAR T product candidate***

Our first platform technology involves the integration of a CD2 co-stimulatory domain designed to counter a target-independent mechanism that leads to resistance to CAR T-cells and other immune therapies. The strength and quality of a T-cell response is dependent not only on cognate antigen recognition, but also on co-stimulation, which involves interaction of one or more co-stimulatory receptors on T cells, such as CD2, with ligands expressed on the surface of tumor cells. Tumor cells can escape CAR T-cell destruction by downregulating the expression of ligands for the co-stimulatory receptors. These ligands include CD58, the ligand of the CD2 co-stimulatory receptor. Alteration of CD58 expression is associated with poor prognosis in LBCL and leads to lack of response to CD19 CAR T cells. Through our platform approach, we created constructs that couple CD2 signaling directly to CAR activation, to enhance activation of the CAR T cells against tumors that do not express CD58.

Our most advanced preclinical programs incorporate CAR multi-specificity to address tumor antigen loss and loss of co-stimulatory CD58. CRG-023, our tri-specific CAR T product candidate, targets tumor cells with three B-cell antigen targets (CD19, CD20 and CD22). One of the binders of this tri-specific T cell will incorporate our CD2 co-stimulation technology that we believe will help improve the treatment of patients that have lost CD58 expression on their tumor cells. We believe that by utilizing our tri-specific CAR T product candidate incorporating our CD2 co-stimulation technology we have the potential to simultaneously prevent relapse due to antigen down-modulation or antigen loss while improving CAR T-cell responses against an important mechanism that tumors employ to evade killing by CAR T cells. We plan to continue to leverage our platform technologies to further advance our additional pipeline programs.

#### ***Preventing emergence of resistance due to loss of co-stimulatory ligands***

The loss of cell surface co-stimulatory proteins on tumors that function to activate T-cell co-stimulatory receptors is a mechanism of development of resistance to CAR T-cell therapies. Tumors that lack the expression of CD58, for example, have been found to be resistant to CAR T cells due to the inability to activate the CD2 receptor on CAR T cells. Approximately 25% of LBCL patients that are eligible for CAR T-cell therapy have mutated or absent CD58 and up to 67% have decreased expression of CD58. In a study of 51 patients with DLBCL treated with Yescarta, the prognosis for patients with mutated or absent CD58 was found to be poor with a median PFS of 3.1 months and

less than 30% achieving CRs. By contrast, patients with intact CD58 expression achieved an 80% CR rate and approximately 60% survived or surviving beyond twelve months.

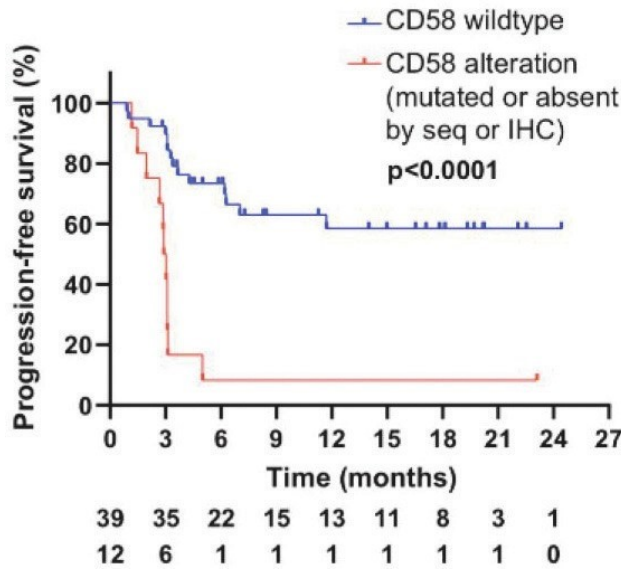


Figure 8. Alteration in CD58 expression was associated with poor prognosis in DLBCL patients treated with Yescarta.

This phenomenon is not confined to DLBCL. A study published in June 2023 demonstrated down regulation of CD58 in patient tumor samples across a wide range of hematologic malignancies including Hodgkin and non-Hodgkin lymphomas (both B-cell and T-cell), including *de novo* disease, suggesting a potential utility for our CD2 platform technology to mitigate immune escape in future therapies for a broad range of hematologic malignancies. The study also demonstrated no correlation with CD58 downregulation and any other B-cell marker (CD19, CD20, CD22 or PAX5), suggesting an independent mechanism of resistance from these cell markers. Further, we believe that this technology has the potential to lead to therapeutic benefit in other cancer indications beyond hematologic malignancies. For example, CD58 expression was reported to be reduced in melanoma patients who are resistant to checkpoint inhibitors. Similarly, sensitivity to bispecific T cell engagers (TCEs), was reported to be dependent on CD58/CD2 signaling.

In order to combat CD58 downregulation, we are developing modified CAR constructs designed to induce CD2 intracellular signaling by a tumor antigen independent of the presence of CD58 on tumor cells, thereby alleviating the need for CD58 binding to the CD2 receptor and removing a common mechanism that may lead to resistance to CD19 CAR T-cell therapy.

The potential of our CD2 platform technology was demonstrated in a cell killing assay using NALM6 tumor cells. Because these cells express CD22, they are attacked and killed by CD22-targeted CAR T cells similar to CRG-022. Those NALM6 cells that lacked expression of CD58 resisted killing by CD22-targeted CAR T cells.

We hypothesized that restoration of CD2 stimulation would resensitize NALM6 cells that lack CD58 expression to killing by CAR T cells. To test this, we created a CAR that incorporated our CD2 technology in a CD19-targeted CAR with the intent of creating a CD2 activator that was dependent on binding to CD19 rather than CD58.

We observed that although NALM6 cells express CD19, treatment with CD19-targeted CAR with CD2 technology did not sustain long-term tumor cell killing *in vitro* on its own. However, when CAR T cells were created that contained both CD22-targeted CAR and CD19-targeted CAR with CD2 technology, we observed efficient killing of NALM6 cells, including those that lacked CD58. We believe this result suggests that a multi-specific CAR T cell incorporating CD2 technology, can improve activity against tumor cells that lack CD58 expression relative to monospecific CAR T cells.

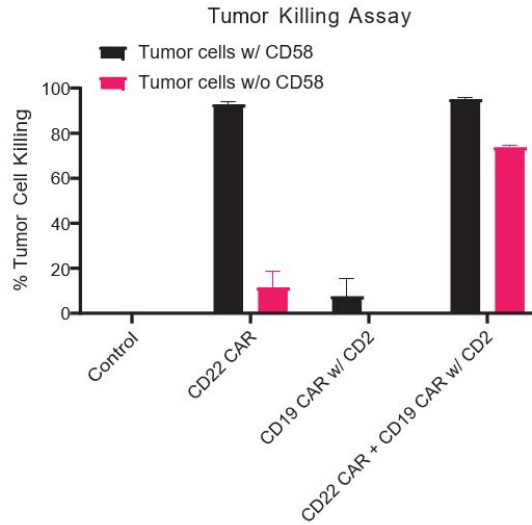


Figure 9. Multispecific CAR T cells incorporating our CD2 technology achieves sustained killing of both CD58+ and CD58- tumor cells

We believe that this CD2 platform technology has the potential to address an important mechanism that tumors employ to evade killing by CAR T cells, across a broad range of cancers.

**CRG-023, a tri-specific CAR T product candidate**

Critical to the long-term success of CAR T-cell therapies is the ability to increase the number of patients who achieve meaningful therapeutic benefits and for whom these benefits have long-term durability. Achieving this additional breadth will likely require approaches that target more than one tumor antigen at a time. This would, we believe, both expand the pool of eligible patients and reduce the frequency of emergence of resistance.

We are developing CRG-023, a tri-specific CAR T product candidate that targets tumor cells with three B-cell antigen targets (CD19, CD20 and CD22).

We believe that, by targeting these three antigens, we will be able to prevent relapse due to antigen down-modulation or antigen loss while giving us optionality for treating multiple types of B-cell malignancies. In addition to the CD22 CAR used in CRG-022, we plan to utilize novel, fully human CAR binders targeting CD19 and CD20 that we believe should decrease the probability of immune cell rejection by patient recipients due to non-native elements. Finally, CRG-023 will incorporate our CD2 co-stimulation technology that we believe will help improve the treatment of patients that have loss or downregulation of CD58 expression on their tumor cells.

In order to evaluate the function of each independent CAR in CRG-023, three Nalm6 B-ALL cell lines were prepared, each expressing only one of the three targeted antigens (CD19, CD20 or CD22). The tri-specific CAR T cell and mono-specific control CAR T cells targeting each antigen were incubated with these Nalm6 cell lines, and the resulting IL-2 secretion – a measure of T cell function– was measured 24 hours later (Figure 15). Each CAR in CRG-023 was able to induce the T cells to secrete IL-2 in response to antigen at levels similar to the mono-specific CAR T cells, thereby demonstrating the independent function of each CAR in CRG-023.

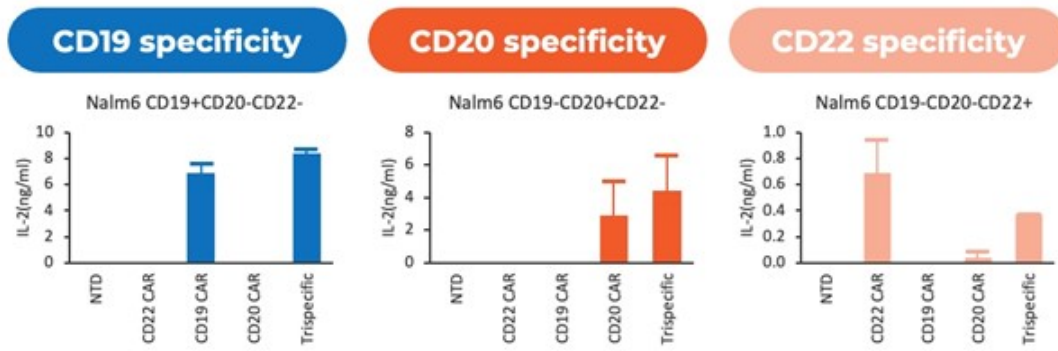


Figure 10. Each CAR in the CARGO tri-specific CRG-023 induced the T cells to secrete IL-2 in response to antigen at levels similar to a mono-specific CAR T control.

In order to evaluate the ability of these tri-specific CAR T cells to eliminate tumors *in vivo*, we employed a mouse model in which a non-Hodgkin lymphoma B cell line called Raji was implanted into immunodeficient NSG mice. These Raji cells express all three antigens (CD19, CD20 and CD22) and were engineered to express luciferase to allow for *in vivo* quantification of tumor burden via bioluminescent flux. On day 0, Raji cells were intravenously implanted and on Day 4, three million CAR T cells were injected, and tumor burden was measured over time. Mono-specific CAR T cells for each CAR used in CRG-023 were prepared as controls. While mono-specific CAR T cells gave partial responses at this dose, our tri-specific CAR T cells reduced bioluminescent flux values down to background levels (Figure 13).

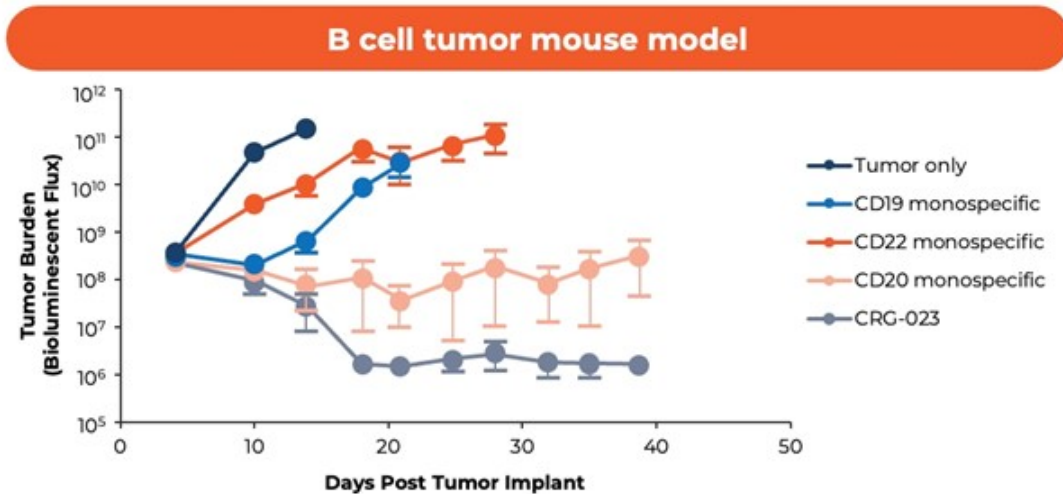


Figure 11 Our tri-specific CAR T cells, CRG-023, showed better *in vivo* antitumor activity against a mouse B cell tumor model (Raji) than mono-specific CAR T cells.

To understand the impact of antigen loss on our tri-specific CAR T cells, three Raji cell lines were engineered with one of the three antigens (CD19, CD20 or CD22) knocked-out (KO). A 1:1:1 mixture of these Raji cells (CD19 KO:CD20 KO:CD22 KO) was injected into immunodeficient NSG mice on day 0. On Day 4, either our tri-specific CAR T cells or monospecific CAR T-cell controls targeting either CD19 or CD22 were injected. Tumor burden was monitored over time by measuring bioluminescent flux. As expected, the mono-specific CAR T cells were unable to control the tumor due to one-third of the cells not expressing their cognate antigen. However, our tri-specific CAR T



cells reduced tumor burden down to background levels (Figure14). These data suggest that our tri-specific CAR T cells maintained activity against tumor cells that do not express one of the three target antigens.

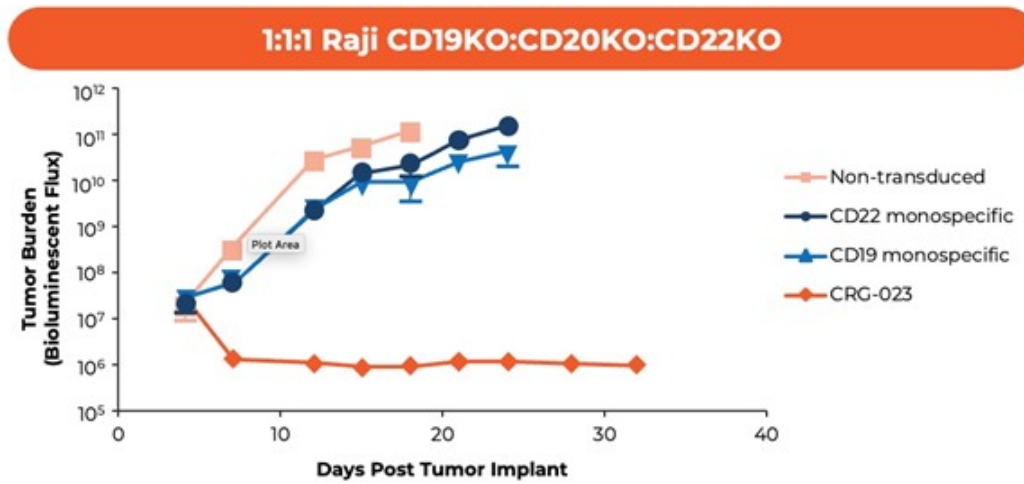


Figure 12. Our tri-specific CAR T cells reduced tumor burden to background levels in an antigen loss in vivo tumor model.

We have initiated preclinical, process development and analytical development efforts to prepare for an IND submission for CRG-023.

We are committed to improving T-cell activation and persistence and addressing immunosuppressive mechanisms in the tumor microenvironment. We believe that our CD2 technology, along with other components of our platform technologies in development, are key to the future of CAR T-cell therapies. We intend to lead the development of these next generation product candidates with our proprietary platform technologies.

**Competition**

Our products will compete with novel therapies developed by biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions, in addition to standard of care treatments.

Potential competitors with autologous CAR T-cell therapies that are either approved or in development include 2seventybio, Autolus Therapeutics, Bristol-Myers Squibb, Janssen and AbelZeta, Gilead Sciences, ImmPACT Bio, Miltenyi, Mustang Bio, Novartis, and Oncternal. Potential competitors with allogenic CAR cell therapies in development include Allogene Therapeutics, Atara Biotherapeutics, Century Therapeutics, CRISPR Cellectis, Fate, Imugene, Nkarta, Poseida Therapeutics, Sana Biotechnology, and Takeda. Autologous CAR T-cell therapies are made with cells obtained from the patient being treated. In contrast, allogenic CAR T-cell therapies are made with cells obtained from a healthy donor and typically include additional genetic modifications and other refinements intended to reduce or ideally eliminate the likelihood of immune rejection or graft versus host disease when infused into patients. Due to the promising therapeutic effect of CAR T-cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies. Competition will also arise from non-cell based immune and other pursued by small-cap biotechnology and large-cap pharmaceutical companies including Abbvie, Amgen Inc, AstraZeneca, Bristol-Myers Squibb, Genmab, Incyte, Merck, Regeneron and Roche.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential 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 products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all our programs are efficacy, safety and reliability of supply.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, as well as for technologies complementary to, or necessary for, our programs.

#### ***Certain competitor data – CD19 CAR T-cell therapies***

There are three currently approved CD19 CAR T-cell therapies for the treatment of LBCL. Select published clinical data from current FDA-approved CD19 CAR T-cell therapies in development for the treatment of LBCL are presented below.

##### *Axicabtagene ciloleucel (Yescarta)*

In a Phase 2 clinical trial of ZUMA-1, a single-arm, multi-center, registrational trial, Yescarta was administered to 101 patients. After 11.6 months of follow-up, the ORR and CR rate were 72% and 51%, respectively. At 18 months, the ORR and CR rate were 82% and 54%, respectively, and Grade 3 or higher CRS and neurologic events occurred in 13% and 28% of patients, respectively. After 2 years of follow-up, the ORR, CR rate and PFS were 83%, 54% and 39%, respectively, as compared to after 5 years of follow-up, where the ORR, CR rate and PFS were 83%, 58% and 32%, respectively.

In a Phase 3 clinical trial of ZUMA-7, a randomized, open-label, multi-center trial, Yescarta was administered to 180 patients and supported the initial treatment in adults with 2L R/R LBCL. After 14.7 months of follow-up, the ORR, CR rate and PFS were 83%, 65% and 50%, respectively, and Grade 3 or higher CRS and neurologic events occurred in 7% and 25% of patients, respectively. After 4 years of follow-up, the ORR, CR rate and PFS were 83%, 65% and 42%, respectively. With an estimated median follow up of 46.7 months overall, the primary analysis of OS showed a statistically significant improvement in the Yescarta arm (55.9% OS at 39 months) compared to the standard therapy arm (46% OS at 39 months), a 27.4% reduction in the risk with death.

##### *Tisagenlecleucel (Kymriah)*

In a Phase 2 clinical trial of JULIET, an open-label, multi-center, single-arm trial, Kymriah was administered to 68 patients. At 9.4 months, the ORR and CR rate were 50% and 32%, respectively, and Grade 3 or higher CRS and neurologic events occurred in 22% and 12% of patients, respectively. At 24 months of follow-up, the ORR and CR rate were 52% and 38%, respectively, as compared to after 40.3 months of follow-up, where the ORR and CR rate were 53% and 39%, respectively. After 36 months of follow-up, the PFS was 31%.

##### *Lisocabtagene maraleucel (Breyanzi)*

In the pivotal TRANSCEND NHL 001 clinical trial, Breyanzi was administered to 192 patients. After 18.8 months of follow-up, the ORR and CR rate were 73% and 54%, respectively, and Grade 3 or higher CRS and neurologic events occurred in 2% and 10% of patients, respectively. After 2 years of follow-up, the ORR, CR rate and PFS were 73%, 53% and 41%, respectively.

In the pivotal Phase 3 TRANSFORM clinical trial, Breyanzi was administered to 92 patients and supported the initial treatment in adults with 2L R/R LBCL. At 6.2 months, the ORR and CR rate were 84% and 66%, respectively, and Grade 3 or higher CRS and neurologic events occurred in 1% and 7% of patients, respectively. After 17.5 months of follow-up, the ORR, CR rate and PFS were 87%, 74% and 58%, respectively.

*ORR and CR rate*

The following reflects the published data on ORR and CR rates of CD19 CAR T-cell therapies for the treatment of 3L+ LBCL after 2 years of follow-up: Yescarta (83% ORR, 54% CR rate), Kymriah (52% ORR, 38% CR rate) and Breyanzi (73% ORR, 53% CR rate).

***Certain competitor data – bispecific T-cell engaging antibodies***

There are two CD20-directed CD3 T-cell engagers for the treatment of LBCL that have received accelerated approval from the FDA. Select published clinical data from current approved CD20-directed CD3 T-cell engagers in development for the treatment of LBCL are presented below. Continued approval for any product receiving accelerated approval may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

*Epcoritamab-bysp (Epkinly)*

In a Phase 2 clinical trial EPCORE NHL-1, an open-label, multi-cohort, multi-center, single-arm, registrational trial, Epkinly was administered to 157 patients. 39% had prior CAR T-cell therapy. The ORR and CR rate were 61% and 38%, respectively. Grade 3 or higher CRS and neurologic events occurred in 2.5% and 0.6% of patients, respectively.

*Glofitamab-gxbm (Columvi)*

In a Phase 2 clinical trial NP30179, an open-label, multi-cohort, multi-center, single-arm, registrational trial, Columvi was administered to 132 patients. 30% had prior CAR T-cell therapy. The ORR and CR rate were 56% and 43%, respectively. Grade 3 or higher CRS and neurologic events occurred in 4.2% and 2.1% of patients, respectively.

**Intellectual property**

Intellectual property (IP) rights are important to the success of our business. We rely on a combination of patent, trademark and trade secret laws in the United States and in jurisdictions outside of the United States, including Australia, Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand, Russia, Singapore, South Africa and the United Kingdom, as well as license agreements, confidentiality and non-disclosure agreements with third parties, and other contractual protections to protect our IP rights, including proprietary technology, know-how, trademarks, trade secrets, and brands.

We protect the proprietary technologies produced by our continuing technological innovation that are important to our business using a combination of approaches, including by filing patent applications that cover our product candidates, platform technologies, and methods of using such candidates and technologies, as well as any improvements to existing inventions that are commercially important to the development of our business. We protect the IP we have licensed from third parties and work collaboratively with our licensors on patent prosecution to ensure we obtain commercially relevant patent protection. We also rely on trademarks, copyrights, trade secrets, and know-how to develop, protect and maintain our other IP. Our commercial success depends in part on our ability to obtain, maintain, enforce and defend our IP rights covering the technology, inventions and improvements that are important to our business, by preventing others from infringing any IP we may own or in-license in the future, preserving the confidentiality of our trade secrets, and operating without infringing, misappropriating or otherwise violating the valid and enforceable IP rights of third parties.

As of February 23, 2024, we owned five pending U.S. provisional patent applications and seven pending Patent Cooperation Treaty (PCT) applications comprising applications drawn to the following technical subject matter: (a) cytokine receptors switch polypeptides and uses thereof; (b) CD2-recruiting chimeric antigen receptors and fusion proteins; (c) compositions and methods for improved immunotherapies; (d) compositions and methods for allogeneic immunotherapies; (e) split receptor switch polypeptides and uses thereof; (f) multiplex cell selection compositions and uses thereof; (g) compositions and methods for immunotherapies; (h) anti-CD22 chimeric antigen receptor (CAR) therapies; (i) compositions and methods for immunotherapies; (j) methods for manufacturing CAR T cells; and (k) modified immune effector cells. Any patents issuing from these patent applications are expected to expire in 2043 or

2044, without taking into account any possible patent term adjustments or extensions. In addition, we have exclusively licensed from the NCI three patent families together comprising seven issued U.S. patents, two pending U.S. patent applications, 15 granted or allowed foreign patents (in Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, and Russia) and six pending foreign patent applications (in Australia, Canada, Europe, Japan, Korea, and Singapore). We have also licensed or optioned from Stanford University four patent families together comprising four pending U.S. patent applications, and 56 pending foreign patent applications (in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Singapore, South Africa and the United Kingdom) that cover a wide range of compositions of matter (including pharmaceutical compositions) and methods (including methods of use) drawn to the following technical subject matter: (a) human monoclonal antibodies specific for CD22; (b) m971 chimeric antigen receptors; (c) bicistronic chimeric antigen receptors and their uses; (d) chimeric antigen receptors with CD2 activation; (e) methods for diagnosing or treating health conditions or optimizing therapeutic efficacy of CAR T cell therapies; (f) recombinant polypeptides for regulatable cellular localization; (g) cell selection methods and related compositions. These patent applications and any patents issuing therefrom are expected to expire between 2029 and 2042, without taking into account any possible patent term adjustments or extensions.

Our ability to maintain our IP rights covering our product candidates, platform technologies, methods of using such candidates and technologies, as well as any improvements to existing inventions that are important to our business will depend on our success in obtaining commercially relevant patent claims and enforcing those claims if necessary. However, our pending provisional and PCT patent applications and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to protect our IP in relation to the commercialization of our products or platform technologies. We also cannot predict the breadth of claims that may be allowed in any patent applications we may own or in-license in the future. Notwithstanding the scope of the patent protection available to us, a competitor could develop competitive technologies and products that are not covered by our IP, and we may be unable to stop such competitor from commercializing such technologies and products.

Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. Because patent applications publish no earlier than 18 months after filing, there may be applications currently unknown to us which may later result in issued patents that our existing or future products or technologies may be alleged to infringe. Additionally, we cannot be certain of the priority of inventions covered by pending third-party patent applications. If third parties prepare and file patent applications in the United States that also claim technology and products to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office (USPTO) to determine priority of invention, which is highly unpredictable and which could result in substantial costs, even if the eventual outcome is favorable to us. In addition, because of the extensive time required for clinical development and regulatory review of technologies and product candidates we may develop, it is possible that, before any of our products can be commercialized, any patent covering a certain product may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In the United States and most other countries, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment (to compensate a patentee for administrative delays by the USPTO in examining a patent application) or patent term extension (to compensate a patent holder for delays associated with regulatory review), or may be shortened if a patent is terminally disclaimed over another patent.

There can be no assurance that the pending provisional or PCT patent applications we own or have in-licensed now or that we may own or in-license in the future will ultimately result in issued patents or that we will benefit from any patent term adjustment or extension. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its claims, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for the entire product lifecycle.

As of March 21, 2024, we had no outstanding IP litigation matters pending nor any threats of litigation against us. In the future, we may need to enforce one or more of the patents issued or licensed to us or to protect our trade secrets or know-how by litigation. We may also need to defend ourselves against claims of patent infringement, trade secret misappropriation, or the like filed by other parties. Litigation can be costly, may divert our attention from other corporate functions and responsibilities, and the outcome is always uncertain. There are numerous possible outcomes to such litigation, including an award of money damages, the grant of a preliminary or permanent injunction preventing us from selling an allegedly infringing product temporarily or permanently, invalidation of one or more claims of the asserted patent(s), or a requirement to grant or take a license subject to the payment of ongoing royalties. Monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and pay significant royalties to such third parties and could prevent us from manufacturing, selling or using our product or technologies, any of which could severely harm our business.

Although we rely on IP rights, including patents, copyrights, trademarks and trade secrets, as well as contractual protections to establish and protect our proprietary rights, we believe that factors such as the technological and creative skills of our personnel, creation of new solutions, features and functionality, and frequent enhancements to our platform technologies are also essential to establishing and maintaining our technology leadership position.

We control access to and use of our proprietary technology and other confidential information through the use of internal and external controls, including confidentiality/nondisclosure agreements and the addition of confidentiality and nondisclosure obligations in company contracts with employees, contractors, suppliers, and partners. We require our employees, consultants and other third parties to enter into confidentiality and nondisclosure agreements and we control and monitor access to our solutions, documentation, proprietary technology and other confidential information. Our policy is to require all employees and independent contractors to sign agreements assigning to us any inventions, trade secrets, works of authorship, developments, processes and other IP generated by them on our behalf and under which they agree to protect our confidential information. In addition, we generally enter into confidentiality agreements with our partners. See the section titled "Risk factors — Risks related to our intellectual property" for a more comprehensive description of risks related to our IP.

## **License agreements**

### *Stanford license agreement*

In August 2022, we entered into a license agreement with the Board of Trustees of Stanford University, as amended in January 2023 (the Stanford License). Pursuant to the terms of the Stanford License, Stanford grants to us a worldwide, exclusive license under certain patent rights, and a worldwide non-exclusive license under certain technology, in each case, owned or controlled by Stanford University to make, use and sell products, methods or services in the field of human therapeutic and diagnostic products. The licensed patent rights cover platform technology relating to the use of CD2/CD58 co-stimulatory signaling in cell therapy.

As consideration for the Stanford License, we paid a one-time, non-refundable upfront license issue fee of \$50,000 and issued 67,605 shares of our common stock, of which 22,317 shares were issued to Stanford University, 27,100 shares were issued to two non-profit organizations that supported the research, and 18,188 shares were issued to various Stanford University inventors. We also agreed to pay annual license maintenance fees of up to \$0.1 million per year, up to \$7.5 million for sales milestone payments, up to \$4.0 million in development milestone payments for each therapeutic product covered by licensed patent rights upon initiation of specific clinical trials or receipt of regulatory approvals, up to \$50,000 in a milestone payment upon achievement of specific commercial milestone event, up to \$0.5 million in a milestone payment upon achievement of certain additional milestone event, a double-digit percentage in milestone payments applicable to products covered by licensed patent rights on the first two licensed non-patent products and, subject to certain royalty reductions, as applicable, low single-digit percentage royalties on net sales of products that are covered by the licensed patent rights or licensed technology. Subject to the terms of the Stanford License, we also agreed to pay Stanford University a certain percentage of non-royalty sublicense related revenue that we may receive from third-party sublicensees.

Stanford University may terminate the Stanford License in the event of a material breach, delinquency in payment or if we provide any materially false report, and any of these events remains uncured for 60 days following written notice of such event. We may terminate the Stanford License in its entirety or on a field-by-field basis at any time upon 30 days' advance written notice to Stanford University.

We agreed to pay Stanford University \$0.3 million if we are acquired by a third party or if we sell all or substantially all of our assets to which the Stanford License relates.

*Oxford license and supply agreement*

In June 2022, we entered into a license and supply agreement (the Oxford Agreement) with Oxford Biomedica (UK) Limited (Oxford Biomedica) for Oxford Biomedica to manufacture and supply to us certain lentiviral vectors (Vectors) for the development and commercialization of T-cells transduced with such Vectors (Licensed Products).

Pursuant to the Oxford Agreement, Oxford Biomedica agrees to provide services related to the development, manufacture and supply of the Vectors and grants to us a non-exclusive worldwide, sub-licensable, royalty-bearing license under certain of Oxford Biomedica's IP rights for us to research, develop, manufacture and commercialize the Licensed Products targeting CD22, and any additional target agreed by Oxford Biomedica and us upon payment of a certain additional target fee.

As consideration for the rights and licenses granted under the Oxford Agreement, we paid Oxford Biomedica an upfront fee of \$0.2 million. We also paid \$0.3 million upon the achievement of a certain development milestone. We agreed to pay up to \$1.0 million of regulatory milestones and \$8.0 million of commercial milestones for each target if such milestones are achieved by Licensed Products directed to such target and up to an aggregate of \$4.3 million if certain milestones related to the transfer of manufacturing capabilities are achieved for each target.

In March 2024, we entered into an amendment (the Oxford Amendment) to the Oxford Agreement. Pursuant to the Oxford Amendment, we and Oxford Biomedica agreed to an amended royalty payment structure for Vectors manufactured by Oxford Biomedica. We will no longer owe royalties on CRG-022 and still will owe royalties in the low single-digit percentages on the net sales of Licensed Products for Vectors used for product candidates other than CRG-022 that are manufactured by Oxford Biomedica and for any Licensed Products (including CRG-022) that are manufactured by us or a third-party following a Technology Transfer (as defined in the Oxford Agreement). We will pay up to \$1.0 million of regulatory milestones for each target if such milestones are achieved by the Licensed Products directed to such target, except for CRG-022, for which a reduced regulatory milestone has been agreed. In addition, we and Oxford Biomedica have agreed a reduced commercial milestone for CRG-022.

Pursuant to the terms of the Oxford Agreement, we solely own any and all IP rights generated under the Oxford Agreement that either relate solely and exclusively to a nucleic acid sequence encoding our CAR that recognizes CD22 or consist solely and exclusively of any improvement or modification of any proprietary materials that we provide to Oxford for use in the performance of services under the Oxford Agreement, or require the use of such proprietary materials or our confidential information.

Unless terminated earlier, the Oxford Agreement will expire when we have no further payments due to Oxford Biomedica under the agreement. We may terminate the Oxford Agreement without cause upon 120 days' advance written notice, but we may be subject to fees involved in cancelling manufacturing slots that Oxford Biomedica has reserved for manufacturing the Vectors under the Oxford Agreement. Either party may terminate the Oxford Agreement or any applicable scope of work or work order in the event of a material breach that is not cured following written notice of such material breach. Either party can also terminate the Oxford Agreement upon insolvency of the other party.

*2022 National Cancer Institute license agreement*

In March 2022, we entered into a license agreement with the U.S. Department of Health and Human Services, as represented by the NCI (the 2022 NCI License), pursuant to which the NCI grants to us an exclusive, worldwide, royalty-bearing license to make, use, sell and import products (Autologous Products) and to practice processes in the field of certain autologously derived CAR T immunotherapies for the treatment of B-cell malignancies that express CD22, and a non-sublicensable exclusive license to make, use, and import, but not sell, products (Allogenic Products) and to practice processes in the field of certain allogeneically-derived CAR T immunotherapies for the treatment of B-cell malignancies that express CD22 for evaluation purposes, with an exclusive option to negotiate a non-exclusive or exclusive commercialization license, in each case, under certain patents owned by the NCI. The exclusive option can be extended once for one year on payment of an extension royalty of \$0.1 million.

As consideration for the licenses granted under the 2022 NCI License, we agreed to pay the NCI a non-refundable license fee of \$0.6 million, of which \$0.2 million was paid in 2022, \$0.1 million was paid in 2023, and the remaining balance of \$0.3 million is payable in two equal annual installments beginning on the second anniversary of the effective date of the agreement. We accrued these non-refundable upfront fees on entering the 2022 NCI License. We agreed to pay up to \$0.2 million in regulatory milestone payments upon making specific regulatory filings, up to \$1.8 million in development milestone payments upon achieving specific clinical milestones comprising the initiation of clinical or registration trials, and up to \$16.0 million in sales milestones upon achievement of specific commercial milestones. Subject to the terms of the agreement, we also agreed to pay low single-digit percentage royalties on net sales of Autologous Products and, if we choose to exercise the exclusive option mentioned above, on net sales of Allogenic Products. We also agreed to pay the NCI a percentage (ranging from low single-digit to low double-digit) of non-royalty revenue received by us for granting a sublicense of the licensed patent rights. Additionally, in the event we are granted a priority review voucher (PRV), we agreed to pay the NCI a minimum of \$5.0 million upon the sale, transfer or lease of each PRV or \$0.5 million upon submission of each PRV for use by the FDA. We also agreed to pay the NCI a royalty based on a percentage (ranging from low single-digit to low double-digits) of the fair market value of the consideration we receive for any assignment of the 2022 NCI License to a non-affiliate (subject to the NCI's prior written consent) or on an allocated portion of the fair value of consideration received in connection with a change in control (including an IPO). On closing of the Company's IPO in November 2023, the change in control milestone was met.

Unless earlier terminated, the 2022 NCI License will expire upon the expiration of the last to expire licensed patent right, but the exclusive license for evaluation purposes and the accompanying exclusive option will expire two years from the effective date of the 2022 NCI License. The option can be extended once for one additional year upon payment of a non-creditable, nonrefundable extension royalty of \$50,000 to the NCI. The NCI may terminate or modify the 2022 NCI License in the event of a material breach, including if we do not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured within 90 days following written notice of such breach or insolvency event. We may terminate the 2022 NCI License, or any portion thereof, at our sole discretion at any time upon 60 days' advance written notice to the NCI.

*2023 National Cancer Institute license agreement*

In February 2023, we entered into a second license agreement with the NCI (the 2023 NCI License) to acquire an exclusive, worldwide, royalty-bearing license under certain patent rights owned by the NCI to make, use, sell and import products and to practice processes in the field of certain CAR T immunotherapies for the treatment of B-cell malignancies, wherein the T cells are engineered to express CD22 in combination with binders, CARs, or other receptors targeting CD19, CD20, and/or CD79b; and at least one of the following: manufacturing the product with the STASH platform technology and/or a technology to activate CD2 signaling in the CAR T cell. As consideration for the license granted under the 2023 NCI License, we agreed to pay the NCI a non-refundable license fee of \$0.3 million, of which \$0.1 million was paid in 2023, and the remaining balance of \$0.2 million is payable in two equal annual installments beginning on the first anniversary of the effective date of the agreement, and up to \$0.1 million in regulatory milestone payments upon making specific regulatory filings, up to \$1.7 million in development milestone payments upon achieving specific clinical trials or registration trials, and up to \$16.0 million in sales milestone upon achievement of specific commercial milestone events. Subject to the terms of the agreement, we also agreed to pay a low single-digit percentage royalties on net sales of Allogenic Products. We also agreed to pay the NCI a low double-digit percentages of non-royalty revenue received by us for granting a sublicense of the licensed patent rights.

Additionally, in the event we are granted a PRV, we agreed to pay the NCI a minimum of \$5.0 million upon the sale, transfer or lease of each PRV or \$0.5 million upon submission of each PRV for use by the FDA. We also agreed to pay the NCI a royalty based on a low single-digit percentage of the fair market value of the consideration that we receive for any assignment of the 2023 NCI License to a non-affiliate (subject to the NCI's prior written consent) or on an allocated portion of the fair value of consideration received in connection with a change in control (including an IPO). On closing of the Company's IPO in November 2023, the change in control milestone was met. As of December 31, 2023, we accrued a total of \$0.3 million of research and development expense related to the change in control royalty for both the 2022 NCI License and the 2023 NCI License.

Unless earlier terminated, the 2023 NCI License will expire upon the expiration of the last to expire licensed patent. The NCI may terminate or modify the 2023 NCI License in the event of a material breach, including if we do not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured within 90 days following written notice of such breach or insolvency event. We may terminate the 2023 NCI License, or any portion thereof, at our sole discretion at any time upon 60 days' advance written notice to the NCI.

## **Government regulation**

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biological product candidates such as those we are developing. We, along with third-party contractors and service providers, will navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies in the US and other countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

### *U.S. biologics development process*

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal, state, local and foreign statutes and regulations. The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory studies in accordance with Good Laboratory Practice (GLP) regulations, and other applicable regulations;
- submission to the FDA of an IND, which must become authorized before human clinical trials may begin;
- approval by an independent institutional review board (IRB), or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice (GCP) regulations to evaluate the safety, purity and potency (or efficacy) of the product candidate for its intended use;
- submission to the FDA of a Biologics License Application (BLA), after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the biologic is produced to assess compliance with current Good Manufacturing Practice requirements (cGMP), to ensure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- satisfactory completion of potential inspection of selected clinical investigation sites to assess compliance with GCP;
- satisfactory completion of an FDA advisory committee review, if required; and



- FDA review and approval of the BLA to authorize commercial marketing of the product for the treatment of one or more specific indications in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for FDA allowance to administer an investigational product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and any effectiveness criteria to be evaluated. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold. If FDA issues a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance with FDA requirements, in which case clinical trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

In addition to the submission of an IND to the FDA, under the NIH Guidelines, supervision of certain human gene transfer trials may also require evaluation and assessment by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to the public health or the environment, and such assessment may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of an investigational product to human subjects and must be conducted under the supervision of one or more qualified investigators in accordance with GCP, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under detailed protocols setting out the objectives of the trial, dosing procedures, subject inclusion and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate amendment to the existing IND must be made for each successive clinical trial protocol and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for unexpected suspected serious adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs or biologics, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB or ethics committee at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the informed consent form that must be provided to each potential trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB requirements and regulations governing experimentation with human subjects. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to and evaluation of certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

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

- Phase 1: The product candidate is initially introduced into healthy human subjects or subjects with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The product candidate is administered to a limited patient population having a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after BLA approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the biologic in order to finalize a process for manufacturing the product in commercial quantities in accordance with cGMP. The manufacturing process must be capable of consistently producing quality batches of the product candidate and the manufacturer must, among other things, develop methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

#### *BLA review and approval process*

Assuming successful completion of all required studies in accordance with applicable regulatory requirements, the results of product development, including among other things, results from preclinical studies and clinical trials, are submitted to the FDA as part of a BLA requesting authorization to market the product candidate for one or more indications. The BLA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, and controls (CMC), and proposed labeling, among other things. Data can come from company-sponsored clinical studies or from alternative sources, such as studies initiated by investigators or other third parties. The submission of a BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved BLA is also subject to an annual program fee. A waiver of user fees may be obtained under certain limited circumstances.

The FDA conducts a preliminary review of a BLA within the first 60 days after submission to determine whether they are sufficiently complete to permit substantive review before accepting the application 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 requested additional information before FDA will review the application. Once filed, the FDA reviews a BLA to determine, among other things, whether the biologic is safe and efficacious and the facility in which it is manufactured, processed, packed, or held meets cGMP designed to assure the product's continued safety, purity and potency. Under the Prescription Drug User Fee Act (PDUFA), guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of an original BLA to review and act on the submission. This review typically takes twelve months from the date the BLA is submitted to the FDA because the FDA has approximately two months to decide whether to accept a BLA application for filing.

The FDA may refer an application for a novel biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation on 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.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving a BLA, the FDA may inspect one or more clinical trial sites to ensure such sites complied with GCP. After the FDA evaluates a BLA and inspects the manufacturing facilities where the investigational product and/or the commercial drug product will be produced, the FDA typically issues either an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the biologic with prescribing information for specific indications. A CRL indicates that the review cycle for the application

is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may include requirements to conduct additional clinical trials, or other significant and time-consuming requirements related to the sufficiency of the clinical data provided, nonclinical studies or CMC-related activities. If a CRL is issued, the sponsor must submit a revised BLA addressing all of the deficiencies identified in the letter or withdraw the application. Even if the applicant submits the requested data and information the FDA may still decide that the BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, referred to as “licensure” by the FDA, such approval may be significantly limited to specific diseases and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require the sponsor of an approved BLA to conduct one or more post-marketing clinical trials designed to further assess a biologic’s safety and efficacy, and may also require testing and surveillance programs to monitor the safety of the product once commercialized and may limit further marketing of the product based on the results of these post-marketing studies. The FDA may also place other conditions on BLA approval, including the requirement for a risk evaluation and mitigation strategy (REMS), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS in conjunction with the BLA, which could include medication guides, physician communication plans or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of any approved products.

In addition, the Pediatric Research Equity Act (PREA), requires a sponsor to conduct pediatric clinical trials for most biologics, as well as for new indications, new dosage forms, new dosing regimens or new routes of administration. Under PREA, original BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe, pure and potent. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the biologic is ready to be approved for use in adults before pediatric clinical trials are complete or that additional data need to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

#### *Orphan designation*

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition 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 to market the same biologic for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The receipt of orphan drug designation for a biologic entitles a party to certain financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors may receive approval of different products for the disease or condition for which the orphan product has exclusivity or obtain approval for the same product but for a different disease or condition for which the orphan product has exclusivity. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the “same drug,” as defined by the FDA, or if the biologic is determined to be contained within the competitor’s product for the same disease or condition. In addition, if an orphan-designated product receives approval for a disease or condition broader than covered in the orphan designation, the product may not be entitled to orphan exclusivity.

*Expedited development and review programs*

The FDA has a number of programs intended to expedite drug development and/or review of an application for marketing authorization for an investigational biologic. For example, the fast-track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Investigational biologics 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 that disease or condition. The sponsor of a fast-track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. Also, for product candidates in development under a fast-track designation, the FDA may agree to review sections of the BLA on a rolling basis before the complete application is submitted if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

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

Certain investigational biologics may also be eligible for regenerative medicine advanced therapy (RMAT) designation. This designation may be available where the product candidate qualifies as an RMAT, meaning that, with limited exceptions, the investigational new drug: (1) is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products; (2) is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such a disease or condition. The RMAT designation provides all the benefits of a Breakthrough Therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review of a BLA submission. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, as discussed below, or through reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites.

Product candidates submitted to the FDA for approval, including product candidates with Fast Track, Breakthrough Therapy, or RMAT designations, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A BLA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of a BLA designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, certain products may be eligible for accelerated approval. A product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that it 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 of alternative treatments or lack thereof. As a condition of approval, the FDA generally requires that a sponsor of a biologic receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials and may require that such confirmatory trials be underway prior to granting accelerated approval. Biologics receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

None of these specific designations or mechanisms for accelerated or expedited review of applications for marketing authorization change the standards for approval but may expedite development or the regulatory approval processes. Even if a product candidate qualifies for one or more of those programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

*FDA regulation of companion diagnostics*

We believe that certain of our product candidates may require an *in vitro* diagnostic (IVD) to identify appropriate patient populations for investigation and/or use of our product candidates. IVDs, often referred to as companion diagnostics, are regulated by FDA as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, IVDs require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval (PMA). Most companion diagnostics for oncology product candidates utilize the PMA pathway.

If use of companion diagnostic is deemed essential to the safe and effective use of a drug product, then the FDA generally will require approval or clearance of the diagnostic for the use indicated on the product label contemporaneously with the approval of the product. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for “In Vitro Companion Diagnostic Devices.” According to the guidance, for novel product candidates, a companion diagnostic device and its corresponding drug candidate should be approved or cleared contemporaneously by FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the IVD may be determined to be a significant risk device under the FDA’s Investigational Device Exemption (IDE) regulations, in which case the sponsor of the IVD will be required to submit and obtain approval of an IDE application, and subsequently to comply with the IDE regulations. However, according to the guidance, if an IVD and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets the requirements of both the IDE regulations and the IND regulations. The guidance provides that, depending on the details of the study plan and degree of risk posed to subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE.

The FDA has generally required IVDs intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously with approval of the therapeutic. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device’s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. In addition, PMAs for certain devices must generally include the results from extensive preclinical studies, as well as from well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for an IVD, the applicant must demonstrate that it produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer’s facilities for compliance with the current Quality System Regulation (QSR), which imposes comprehensive testing, control, documentation and other quality assurance requirements.

If the FDA’s evaluation of the PMA application is favorable, the FDA may issue an approvable letter requiring the applicant’s agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA’s evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and the data submitted in an amendment to the PMA. If and when the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant.

The PMA may also include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the IVD, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing.

After an IVD is approved for marketing, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. IVD manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which currently cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

*Post-approval requirements*

Biologics are subject to rigorous and ongoing regulation by the FDA following receipt of a marketing authorization, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their manufacturing facilities with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which imposes certain procedural and documentation requirements upon drug developers and third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort on production and quality control to maintain compliance with cGMP and other compliance requirements.

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

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

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

#### *Biosimilars and exclusivity*

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in respect of safety, purity, and potency, can be shown through analytical studies, animal studies, and one or more clinical studies. Interchangeability requires that a proposed biosimilar product can be substituted for the reference product and the biosimilar manufacturer must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient.

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

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds an extra six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

#### *Other healthcare laws*

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, and physician payment transparency laws and regulations regarding drug pricing and payments or other transfers of value made to physicians and other licensed healthcare professionals as well as similar foreign laws in jurisdictions where the company does business outside the United States. Violation of any of such laws or any other governmental regulations that apply may result significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement fines, additional reporting requirements and oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/ or imprisonment.

#### *Coverage and reimbursement*

Successful sales of our drug candidates in the U.S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time-consuming and costly.

Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage). For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third-party reimbursement for our investigational drug products, if approved, or a decision by a third-party payor to not cover our investigational drug products could have a material adverse effect on our sales, results of operations and financial condition.

General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a drug candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or significant related taxes or fees.

#### *U.S. healthcare reform*

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs.

For example, in March 2010, the Affordable Care Act, or ACA, was enacted in the United States and substantially changed the way healthcare is financed by both the government and private insurers. The ACA contains provisions that may reduce the profitability of drug products. Among other things, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered outpatient drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; and increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in place in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update its guidance documents as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, even though this part of the IRA remains subject to ongoing legal challenges. The impact of the IRA on the pharmaceutical industry and our business cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.



At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or 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 addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Existing healthcare reform measures, as well as the implementation of additional cost containment measures or other reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

### **Data privacy and security**

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

### **Corporate information**

We were incorporated in the state of Delaware in December 2019 as Syncopation Life Sciences, Inc. and changed our name to CARGO Therapeutics, Inc. in September 2022. Our principal executive offices are located at 1900 Alameda Las Pulgas, Suite 350, San Mateo, California, and our telephone number is (650) 379-6143. Our corporate website address is [www.cargo-tx.com](http://www.cargo-tx.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.

### **Employees and human capital resources**

As of December 31, 2023, we had approximately 116 full-time employees. None of our employees are represented by a labor union or party to 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 additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

### **Legal proceedings**

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

### **Available information**

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, and related amendments, exhibits and other information with the Securities and Exchange Commission (SEC). You may access and read our filings without charge through the SEC's website at [www.sec.gov](http://www.sec.gov) or through our website at <https://investors.cargo-tx.com/financial-information/sec-filings>, as soon as reasonably practicable after such materials are electronically filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. 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.

## **Item 1A. Risk Factors.**

### **Risk factors**

*Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, as well as the other information contained in this Annual Report on Form 10-K, including “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K, before making investment decisions regarding our common stock. The risks described below are not the only ones facing us. 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, reputation or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment.*

### **Risk Factor Summary**

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled “Risk factors” immediately following this summary. These risks include, among others, the following:

- We are a clinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.
- Our limited operating history may make it difficult to evaluate our prospects and likelihood of success.
- The substantial obligations from our license agreements may result in dilution to our stockholders, may be a drain on our cash resources or may cause us to incur debt obligations to satisfy the payment obligations.
- If we are unable to successfully identify, develop, obtain regulatory approval and ultimately commercialize any of our current or future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.
- We have experienced rapid operational growth since our inception in December 2019, and expect to continue to grow in the future as our clinical and preclinical trials progress, we begin to advance the development of new and current product candidates and our headcount increases. If we fail to effectively manage our growth, we may not be able to execute on our business objectives.
- Our ability to develop our product candidates and our platform technologies, as well as our future growth, depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.
- We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- We rely on third parties to conduct our clinical trials, manufacturing and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.
- We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

**Risks related to our limited operating history, financial condition and need for additional capital**

*We are a clinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.*

We are a clinical-stage biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant losses since our inception in December 2019, have no products approved for commercial sale, have not generated any revenue from product sales, have financed our operations principally through private placements of convertible preferred stock, convertible promissory notes and our initial public offering of our common stock and expect to incur significant losses for the foreseeable future. We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Our net loss was \$98.1 million and \$41.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$145.1 million. Our losses have resulted principally from expenses incurred in connection with our research and development activities, including our clinical and preclinical development activities, as well as the buildout of our platform technologies such as our CD2 platform, and from general and administrative costs associated with our operations.

We have devoted a significant portion of our financial resources and efforts to building our organization, conducting research and development, identifying and developing potential product candidates, executing preclinical studies and clinical trials, building and enhancing our platform technologies, organizing and staffing our company, business planning, establishing, maintaining and protecting our intellectual property portfolio, raising capital and providing general and administrative support for these operations. We are in the early stages of clinical development and have not completed development and commercialization of any of our product candidates.

We expect our expenses and operating losses will continue to increase substantially for the foreseeable future as we expand our research and development efforts, expand the capabilities of our platform technologies, conduct clinical trials and preclinical studies, seek regulatory approval and commercialization of our product candidates and operate as a public company. We anticipate that our expenses will continue to increase substantially as we:

- continue clinical and preclinical development of our current and future product candidates and initiate additional clinical trials and preclinical studies;
- continue to build out and enhance our platform technologies;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical and preclinical development, manufacturing and commercialization efforts;
- to the extent we acquire or in-license additional product candidates, technologies and other assets for our business;
- continue to develop, perfect, maintain and protect our intellectual property portfolio; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

To become and remain profitable, we must succeed in identifying, developing, conducting successful clinical trials, obtaining regulatory approval for and eventually commercializing, manufacturing and supplying products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of our product candidates, continuing to discover and develop additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, developing manufacturing processes and methods, devising and implementing processes for transferring technology and manufacturing processes to a network of third-party manufacturing sites, establishing necessary quality control, ensuring current Good Manufacturing Practice (cGMP) readiness, establishing marketing capabilities, commercializing and ultimately selling any products. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve

or sustain profitability or to meet outside expectations for our profitability, the price of our common stock could be materially adversely affected.

Because of the numerous risks and uncertainties associated with pharmaceutical and biotechnology products and drug development, including the development of cell therapy product candidates, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration (FDA) or comparable foreign regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in commencing or completing our clinical trials or the development of any of our product candidates, our expenses could increase and commercial revenue could be further delayed and become more uncertain, which will have a material adverse impact on our business.

***Our limited operating history may make it difficult to evaluate our prospects and likelihood of success.***

We are a clinical-stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. Since our inception in December 2019, we have devoted substantially all of our resources and efforts to building our organization, in-licensing technologies, building our platform technologies, identifying and developing potential product candidates, preparing for, and as the case may be, initiating clinical trials and preclinical studies, developing manufacturing processes and methods, devising and implementing processes for transferring technology and manufacturing processes to a network of third-party manufacturing sites, ensuring supply of critical reagents and final products to support the clinical trials and eventually commercialization, organizing and staffing our company, business planning, establishing, maintaining and protecting our intellectual property portfolio, raising capital and providing general and administrative support for these operations. All of our product candidates are in either clinical development or in preclinical stages of development, and we have not yet demonstrated our ability to successfully complete any late-stage or registration clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third-party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, it could have a material adverse effect on our business.

***We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.***

Developing biotechnology products, including conducting clinical trials and preclinical studies, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and our expenses will continue to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials of, and seek regulatory approval for, our current product candidates and future product candidates we may develop or otherwise acquire. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed our product candidates or certain proprietary products used in the manufacturing of our clinical products, including The Board of Trustees of the Leland Stanford Junior University (Stanford University), The National Cancer Institute (the NCI) and Oxford Biomedica. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate, including manufacturing and supply costs, as well as costs associated with establishing a sales and end-to-end supply chain management infrastructure. To date, we have funded our operations principally through private financings and our recently completed initial public offering. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical and preclinical development and manufacturing of our product candidates,

continuing to develop and enhance our platform technologies, commence additional clinical trials and preclinical studies and continue to identify and develop additional product candidates.

In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and end-to-end supply chain management between the treatment sites and manufacturing sites. Furthermore, following the completion of our initial public offering, we have incurred, and expect to continue to incur, additional costs as we operate as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future regulatory approval or commercialization efforts.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. We may also raise additional financing on an opportunistic basis in the future. We expect to continue to expend significant resources for the foreseeable future. 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. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with developing and enhancing our platform technologies, including our current CD2 platform;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any future milestone, royalty or other payments due in connection with such acquisition or license;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates, including the costs associated with end-to-end supply chain management between the treatment sites and manufacturing sites;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and end-to-end supply chain management, for any of our product candidates for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive regulatory approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;

- addressing any potential interruptions or delays resulting from factors related to pandemics, such as the COVID-19 pandemic, and adverse political events such as government shutdowns;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products and technologies.

Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations. Because of the numerous risks and uncertainties associated with research, product development and commercialization of product candidates, we are unable to predict the timing or amount of our working capital requirements or when or if we will be able to achieve or maintain profitability.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives and adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash and cash equivalents, any future equity or debt financings and upfront and milestone and royalty payments, if any, received under any future licenses or collaborations. We do not have any committed external source of funds. If 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 our common stock. In addition, the possibility of such issuance may cause the trading price of our common stock to decline. Debt financing and preferred equity financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, supply or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of common stock. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

***The substantial obligations from our license agreements may result in dilution to our stockholders, may be a drain on our cash resources or may cause us to incur debt obligations to satisfy the payment obligations.***

In connection with our recent license agreements, we entered into arrangements whereby the counterparties to such agreements are entitled to substantial contingent consideration payments upon the occurrence of certain events. For example, under the terms of our license agreement with Stanford University, in addition to the annual license maintenance fees of up to \$0.1 million per year, we may also be required to pay up to \$12.0 million in milestone payments upon achievement of specific intellectual property, clinical, regulatory and commercial milestone events. In addition, under this license agreement we will be obligated to pay low single-digit percentage royalties on net sales. We are also obligated to pay Stanford University a percentage of non-royalty revenue received by us from our right to sublicense at defined percentages.

In addition, under the terms of our license agreement with Oxford Biomedica for the manufacture and supply of lentiviral vectors for clinical and potentially commercial purposes, we may also be required to pay up to \$9.3 million if certain development, regulatory and commercial milestones are achieved. Additionally, we are obligated to pay low single-digit percentage royalties on net sales of products generated under the Oxford Agreement. Further, under the

terms of our license agreements we entered into with the NCI in 2022 and 2023, pursuant to which we obtained exclusive worldwide, royalty-bearing licenses under certain patent rights to research, develop and commercialize products covered by such licensed patents, we may be required to pay up to \$18.0 million and up to \$17.8 million in milestone payments upon achievement of specific intellectual property, and clinical and commercial milestone events, respectively, and low single-digit percentage royalties on net sales of products incorporating the licensed patent rights from the NCI. Additionally, under the terms of each license agreement with the NCI, in the event we are granted a priority review voucher (PRV), we would be obligated to pay the NCI a minimum of \$5.0 million upon the sale, transfer or lease of the PRV or \$0.5 million upon submission of the PRV for use by the FDA.

In order to satisfy our obligations to make these payments, if and when they are triggered, we may need to issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash and cash equivalents or incur debt obligations to satisfy the payment obligations in cash, which may adversely affect our financial position. In addition, these obligations may impede our ability to raise money in future public offerings of debt or equity securities or to obtain a third-party line of credit.

See the section titled “Business — License agreements” elsewhere in this Form 10-K for additional information regarding these agreements.

### **Risks related to our business**

***If we are unable to successfully identify, develop, obtain regulatory approval and ultimately commercialize any of our current or future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.***

Our ability to generate revenue from sales of any of our approved product candidates, which we do not expect will occur for at least the next several years, if ever, depends heavily on the successful identification, development, regulatory approval and eventual commercialization of any product candidates, which may never occur. We have invested substantially all of our efforts and financial resources in acquiring or in-licensing our current product candidates and conducting clinical trials and preclinical studies. We have never generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for or commercialize, a marketable product. All of our product candidates will require significant clinical development, regulatory approval, establishment of sufficient manufacturing supply, including commercial manufacturing supply, and may require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

The successful development of our product candidates will depend on several factors, including, but not limited to, the following:

- successful and timely completion of clinical trials and preclinical studies for which the FDA, or any comparable foreign regulatory authority, agree with the design, endpoints or implementation;
- sufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- receiving regulatory allowances or authorizations for conducting future clinical trials;
- initiation and successful patient enrollment in, and successful and timely completion of, clinical trials on a timely basis;
- if we are required to supplement our clinical development plans to include additional clinical trials or studies, such as the addition of a double-blind, placebo-controlled, randomized study of CRG-022;
- the frequency and severity of adverse events in clinical trials;
- maintaining and establishing relationships with contract development and manufacturing organizations (CDMOs), contract research organizations (CROs) and clinical sites for the clinical development of our product candidates both in the United States and internationally;

- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe, pure and potent, or effective as for its intended uses;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of regulatory approvals for our product candidates from applicable regulatory authorities;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- the extent of any post-marketing commitments or requirements agreed to with applicable regulatory authorities;
- establishing, scaling up and scaling out, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved, including ability to produce final product using our intended commercial manufacturing process when applied to using patient cells as starting material;
- the protection of our rights in our intellectual property portfolio; and
- our ability to compete with other therapies.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially adversely affect our business, financial condition and results of operations.

Additionally, clinical or regulatory setbacks to other companies developing similar products or within adjacent fields, including those in gene editing and gene therapy and allogenic cell-based therapies, may impact the clinical development of and regulatory pathway for our current or future product candidates, or may negatively impact the perceptions of value or risk of our technologies.

***We have experienced rapid operational growth since our inception in December 2019, and expect to continue to grow in the future as our clinical trials progress, we begin to advance the development of new product candidates and as our headcount increases. If we fail to effectively manage our growth, we may not be able to execute on our business objectives.***

We have experienced rapid growth since our inception in December 2019, and expect to continue to grow in the future. For example, as of December 31, 2019, we had no full-time employees and, as of December 31, 2023, we had grown to approximately 116 full-time employees. In addition, we have developed a broad portfolio of product candidates and discovery programs that includes one product candidate in a potentially pivotal Phase 2 clinical trial. We expect continued growth in the number of our employees and the scope of our operations, particularly as we continue our current and future clinical trials and preclinical studies, initiate and conduct IND-enabling studies and build out our clinical operations, as well as our platform technologies.

To manage our anticipated future growth, we will continue to implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel. Due to the complexity in managing a company that has scaled very quickly and anticipates continued growth, we may not be able to scale our headcount and operations effectively to manage the expansion of our product pipeline or recruit and train the necessary additional personnel. As our operations expand, we also expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining and motivating additional employees; managing our internal development efforts effectively, including the clinical development and FDA review processes for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems and procedures.



We currently rely on certain independent organizations, advisors and consultants to provide certain services, including strategic, financial, business development and research and development services, as well as certain aspects of regulatory approval and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants or contract manufacturing organizations is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on reasonable terms, or at all.

***If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business will be harmed.***

We have estimated and may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones have and may include our expectations regarding the commencement or completion of clinical trials and preclinical studies, data readouts, the submission of regulatory filings, the receipt of regulatory approval or the realization of other commercialization objectives. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve announced milestones in the expected timeframes, the commercialization of the product candidates may be delayed, our credibility may be undermined, our business and results of operations may be harmed and the trading price of our common stock may decline.

***Our ability to develop our product candidates and our platform technologies, as well as our future growth, depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.***

Our success depends upon the continued contributions of our key management, scientific and clinical personnel, many of whom have been instrumental for us and have substantial experience with our product candidates and platform technologies. Given the specialized nature of our product candidates and our platform technologies there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific or technical qualifications specific to each program. The loss of key personnel, in particular our senior leadership team, would delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

In addition, our research and development programs, as well as the development and enhancement of our platform technologies depend on our ability to attract and retain highly skilled scientists, particularly in California. There is powerful competition for skilled personnel in these geographical markets, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

***We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain regulatory approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

With the proliferation of new drugs and therapies for our target indications, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical. Our competitors may, among other things:

- have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do;
- develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products and technologies;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition and results of operations could be materially adversely affected. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products approaches may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates.

In addition, any collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition and results of operations.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

Because we have limited financial and managerial resources, we focus on product candidates, research programs and platform technologies that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other platform technologies or product candidates or for other indications that later prove to have

greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future product candidates, research programs and platform technologies for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

***Our product candidates and platform technologies are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval.***

We have concentrated our research and development efforts on our engineered T cell therapy, including related product candidates and platform technologies, and our future success depends on the successful development of this therapeutic approach. We are in the early stages of developing our pipeline and platforms and there can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EMA and FDA for existing CAR T therapies may not be indicative of what these regulators may require for approval of our product candidates. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from other CAR T therapies that have previously been approved. Unexpected clinical outcomes would significantly impact our business.

***Any product candidates that we may develop will be novel and may be complex and difficult to manufacture, and if we experience manufacturing problems, it could result in delays in development and commercialization of such product candidates or otherwise harm our business.***

Our product candidates involve or will involve novel technology and will require processing steps that are more complex than those required for most small molecule drugs, resulting in a relatively higher manufacturing cost. Moreover, unlike small molecules, the physical and chemical properties of biologics generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that such product will perform in the intended manner. Although we intend to employ multiple steps to control the manufacturing processes for our product candidates, we may experience manufacturing issues with any of our product candidates, critical reagents or raw materials that could cause production interruptions, including contamination, equipment or reagent failure, improper installation or operation of equipment, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error, disruptions in the operations of our suppliers, inconsistency in cell growth and variability in product characteristics. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA or other comparable applicable standards or specifications with consistent and acceptable production yields and costs. 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 the manufacturing facilities in which such product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Our manufacturing process for any CAR T-cell therapy product candidate that we develop will be susceptible to product loss or failure due to the quality of the raw materials, failure of the products to meet specifications, logistical issues associated shipping such material to the manufacturing site, freezing the manufactured product, shipping the final product globally, thawing and infusing patients with such product. Problems with the manufacturing process, even minor deviations from the normal process, could result in

product defects or manufacturing failures that result in lot failures, delays in initiating or completing clinical trials, product recalls, product liability claims or insufficient inventory.

As product candidates are developed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is possible that various aspects of the development program, such as manufacturing process and methods, may be altered along the way in an effort to help optimize processes and results. Such changes carry the risk that they will not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently from the previous Phase 1 clinical trials and affect the results of future clinical trials or our reliance on results of trials that have previously been conducted using the product candidate in its previous form. If the manufacturing process is changed during the course of product development, we may be required to repeat some or all of the previously conducted trials or conduct additional bridging trials or alternatively, we may need to re-develop the manufacturing process and methods, which could increase our costs and delay or impede our ability to obtain regulatory approval.

In addition, the facilities used by us and our contract manufacturers to manufacture our product candidates must be evaluated for the manufacture of our product candidates by the FDA or foreign regulatory authorities pursuant to inspections that will be conducted after we submit a Biologics License Application (BLA) to the FDA, or similar foreign applications to foreign regulatory authorities. We do not control the manufacturing process of our contract manufacturers and are dependent on their compliance with cGMP or similar foreign requirements for their manufacture of our product candidates.

The FDA and other foreign regulatory authorities may require us to submit samples of any lot of any product that may receive approval together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business.

***Certain license agreement counterparties currently conduct clinical trials under their own Investigational New Drug Applications (INDs), which could generate unknown or unexpected clinical results outside of our control.***

Certain of our license agreement counterparties continue to conduct clinical trials with an investigative candidate with the same CAR sequence as CRG-022. In addition, the Phase 1 trial of CRG-022 is ongoing, with the investigators on such trial continuing to release cuts of clinical data at different time points. If either of these activities generate unforeseen or unexpected efficacy or safety data, we may need to refer to such data in our regulatory filings, or otherwise disclose this information, which could harm our business or regulatory strategy if the data are negative.

In addition, we do not anticipate being able to incorporate any prior CRG-022 data from studies conducted under third-party INDs in future regulatory filings. As a result, we may need to conduct additional clinical trials and could be limited in the scope of the labels we pursue, among other adverse consequences. The consequences of any of the foregoing could be costly to us and otherwise harm our business.

***The estimates of market opportunity and forecasts of market growth included in this Annual Report on Form 10-K and our other public filings or press releases may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.***

We intend to initially focus our product candidate development on treatments for various lymphomas. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts we may provide to the market are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. For example, the observed persistence of CD22 expression following patients becoming relapsed or refractory to CD19 CAR T-cell therapy may not be as high as we expect. Similarly, the percentage of the population with CD22 expression could be lower than we anticipate. In both instances, the pool of potential patients that our CD22 product candidates could address could be substantially smaller than we anticipate. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market with such patients, for example, being too sick to receive treatment. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

***Our business is subject to risks arising from epidemic diseases, such as the COVID-19 pandemic.***

The COVID-19 pandemic continues to impact worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, contractors, including our CROs, CDMOs, suppliers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. While it is not possible at this time to estimate the full impact that COVID-19 could have on our business, the continued spread of new variants of COVID-19 and the measures taken by the governments of countries affected could, in addition to disrupting our clinical trials, adversely impact other aspects of our business and operations. The COVID-19 pandemic and mitigation measures have also had 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. The extent to which the COVID-19 pandemic, or any other pandemic, impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

***Even if approved, our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition and results of operations.***

Even if the FDA or any comparable foreign regulatory authority approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Additionally, the product candidates that we are developing are based on our proprietary platforms, which are new technologies. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors, including:

- the timing of market introduction of the product candidate, as well as competitive products;
- the clinical indications for which a product candidate is approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- the terms of any approvals and the countries in which approvals are obtained;
- the number and clinical profile of competing products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to provide acceptable evidence of safety and efficacy;

- the prevalence and severity of any side effects;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- the effectiveness of sales and marketing efforts;
- approval of other new therapies for the same indications;
- marketing, manufacturing and supply support;
- adverse publicity about our product candidates;
- potential product liability claims;
- availability of coverage, adequate reimbursement and sufficient payment from health maintenance organizations and other insurers, both public and private, for our product candidates, or the procedures utilizing our product candidates, if approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and
- other potential advantages over alternative treatment methods.

If our product candidates are approved but fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

***We currently have no marketing, sales or supply chain infrastructure and we intend to either establish a sales and marketing infrastructure or outsource this function to a third-party. Either of these commercialization strategies carries substantial risks to us.***

Given our stage of development, we currently have no marketing, sales and end-to-end supply chain management capabilities. If any of our product candidates complete clinical development and are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting end-to-end supply chain management capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third-party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. We have no prior experience as a company in the marketing, sale and end-to-end supply chain management 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.

To the extent that we enter into collaboration agreements with respect to marketing, sales or end-to-end supply chain management, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks, including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy.

If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition and results of operations.

***We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price.

Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain regulatory approval for any of our product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired.

***We may not realize the benefits of technologies that we have acquired, or will acquire in the future, or other strategic transactions that we have or will consummate.***

Our platform represents an aggregation of innovation and technology from multiple companies and academic institutions, including the NCI, Oxford and Stanford University. Further, a key component of our strategy is to acquire and in-license technologies to support the growth of our product pipeline, as well as to build upon and enhance our platform technologies. As such, we actively evaluate various strategic transactions on an ongoing basis. We may acquire other assets, businesses, products or technologies, as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions and any future strategic transactions depends on the risks and uncertainties involved including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;

- diversion of management time and focus from operating our business to management of acquisition and integration efforts, strategic alliances or joint ventures challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers;
- possible write-offs or impairment charges relating to acquired businesses or joint ventures; and
- challenges resulting from the COVID-19 pandemic making it more difficult to integrate acquisitions into our business.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses, impairments or write-offs of goodwill or impairments and write-offs of in-process research and development assets, any of which could harm our financial condition.

***Our information technology systems, or those used by our third-party contract research organizations or other contractors or consultants, may fail or suffer security breaches.***

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

Despite the implementation of security measures, our information technology systems and those of our CROs, CDMOs and other contractors and consultants are vulnerable to attack and damage or interruption from a variety of threats, including computer viruses and malware (e.g., ransomware), malicious code, natural disasters, terrorism, war, telecommunications and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated national-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. Although to our knowledge we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and negatively affect our operations, it could result in a material disruption of our development programs and our business operations. Further, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures or our other data protection efforts and our investment in information technology, or those of third parties on which we rely, will be fully implemented, complied with or effective to prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. 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. 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.

For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in an actual or perceived loss of, or damage to, our data or applications, or inappropriate disclosure of Confidential Information, the further development and commercialization of our product candidates could be delayed.

Any such security compromise or other event that leads to actual or suspected, or is alleged to lead to, unauthorized access, use, or disclosure of Confidential Information, including personal information regarding our clinical trial subjects or employees, could also harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and fines or mandatory corrective action, and otherwise subject us to liability and proceedings (such as class actions), including under laws and regulations that protect the privacy and security of personal information, and/or significant incident response, system restoration or remediation and future compliance costs, which could adversely effect our results of operations, business or financial condition.

Further, we rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, 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 our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their 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' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. We have and will enter into collaboration, license, contract research and/or manufacturing relationships with organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect and 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, and we may be at heightened risk of losing our proprietary intellectual property rights around the world, including outside of such countries, to the extent such theft or intrusion destroy the proprietary nature of our intellectual property.

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 data 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.

***We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our 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; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.***

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, processing) personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials and sensitive third-party data. Our data processing

activities subject us to numerous data privacy and security obligations, 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 information privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws. For example, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, HIPAA), imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information, such as information we may obtain from research institutions from which we obtain clinical trial data. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. The California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, (collectively, CCPA) requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Other states have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these laws, like the CCPA, may also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais (LGPD)) (Law No. 13,709/2018) and China's Personal Information Protection Law (PIPL) impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20.0 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of the annual global revenue of a non-compliant undertaking, 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.

In the ordinary course of business, we may 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 European Economic Area (EEA) and the United Kingdom (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 similarly stringent interpretations of their 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 and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, the EU-U.S. Data Privacy Framework (DPF), and the UK Extension to the DPF (which allows for transfers from the EEA or UK to U.S.-based organizations who self-certify compliance under the DPF), 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, the UK 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 and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

Our employees and personnel may use generative artificial intelligence (AI) technologies to perform their work, and the use of such generative AI in connection with our Confidential Information may result in leaks, disclosure, or otherwise unauthorized or unintended access to such information, including if such information is used to further refine and train the underlying generative AI models. The disclosure and use of personal information in generative AI

technologies is subject to various privacy laws and other privacy obligations and governments have passed and are likely to pass additional laws regulating generative AI. Further, our ability to continue to develop or use such technologies may depend on access to specific third-party software and infrastructure, such as processing hardware or third-party AI models, and we cannot control the availability or pricing of such third-party software and infrastructure, especially in a highly competitive environment. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

***Negative public opinion and increased regulatory scrutiny of research and therapies involving gene editing may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.***

The gene-editing technologies that we use are novel. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our product candidates. In addition, given the novel nature of gene engineering technologies, governments may place import, export or other restrictions in order to retain control or limit the use of the technologies. Increased negative public opinion or more restrictive government regulations either in the United States or internationally, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates.

#### **Risks related to the regulatory environment for the development and commercialization of our product candidates**

***The regulatory landscape that will apply to development of our product candidates is rigorous, complex, uncertain and subject to change, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals.***

All of our product candidates are based on cell therapy technology, and our future success depends on the successful development of product candidates utilizing our novel approach. We cannot assure you that any development problems we or other cell therapy companies experience in the future related to such technology will not cause significant delays or unanticipated costs in the development of our product candidates, or that such development problems can be solved. In addition, the clinical study requirements of the FDA, and other regulatory agencies, as well as the criteria these regulators use to determine the safety, purity, potency or efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities. Further, as we are developing novel treatments for diseases in which there may be limited clinical experience, there is heightened risk that the FDA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, relatively few cell therapy products have been approved by the FDA or comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States or other jurisdictions. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval in their respective jurisdictions.

Regulatory requirements governing cell therapy products have evolved and may continue to change in the future. For example, the FDA has established the Office of Therapeutic Products within its Center for Biologics Evaluation and Research (CBER), to consolidate the review of cell therapy and comparable products, as well as the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions.

For example, the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) require supervision of human gene transfer trials, including evaluation and assessment 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. The IBC assesses the safety of the research and identifies any potential risk to the public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

We are subject to significant regulatory oversight by the FDA in connection with our clinical trials, and in addition, the applicable IBC and Institutional Review Board (IRB) of each institution at which we conduct clinical trials of our product candidates, or a central IRB if appropriate, may need to review and approve the proposed clinical trial prior to initiation.

Changes in applicable regulatory guidelines for product candidates such as ours may lengthen the regulatory review process, require us to perform additional studies or trials beyond those we contemplate, increase our development costs, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with evolving regulations and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we may anticipate. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all, and could seriously harm our business.

***Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.***

Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process, including due to factors that are beyond our control. The historical failure rate for product candidates in our industry is high. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. For example, although we believe the results from Stanford University's Phase 1 clinical trial of its CD22 CAR T-cell therapy under its own IND support further development of this product candidate, there is no guarantee we will observe similar results in our ongoing Phase 2 clinical trial of CRG-022 being conducted under our own IND due to a variety of factors which we do not have control over. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and regulatory authorities may not agree with the conclusions we draw from our clinical trials and preclinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety, purity, potency or efficacy of the product candidate in humans. We have limited experience in conducting clinical trials, and as an organization, have not yet completed a clinical trial for any of our product candidates.

Prior to initiating clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical or non-clinical studies, or complete additional activities relating to chemistry, manufacturing and controls (CMC) for any product candidate before such authorities allow us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. In particular, the manufacturing of autologous CAR T-cell therapies remains an emerging and evolving field. Accordingly, we expect CMC-related topics, including product specifications, will remain a focus for such regulatory authorities during their reviews of our applications. Moreover, even as we continue our current Phase 2 clinical trial and commence new clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The timing for commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- if we are required to supplement our clinical development plans to include additional clinical trials or studies, such as the addition of a double-blind, placebo-controlled, randomized study of CRG-022 as part of the potentially pivotal Phase 2 clinical trial;
- any failure or delay in reaching an agreement with CROs, CDMOs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CDMOs and trial sites;
- the level of CD22 expression in the patient population in the trial not aligning with our expectations;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more IRBs or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs or CDMOs to perform in accordance with Good Clinical Practice (GCP) requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of necessary critical reagents and of our product candidates for use in our clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;

- subjects experiencing severe or serious unexpected treatment-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a CDMO delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process, or failure of our CDMOs to produce clinical trial materials in accordance with cGMP regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such 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 applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and political and economic risks, including war, relevant to such foreign countries.

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

In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

***We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials will depend, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. 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 trial's conclusion as required by the FDA or other comparable regulatory authorities. The conditions for which we currently plan to evaluate our product candidates are orphan or rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment in clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- difficulty identifying and enrolling patients for clinical trials to expand into earlier lines of LBCL;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of such trials before completion.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs, CDMOs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, may lead us to abandon one or more clinical trials altogether, or may lead the FDA and other regulatory authorities to require us to conduct additional clinical trials before we are able to seek regulatory approvals for our product candidates, if ever. Any enrollment issues in our clinical trials may therefore result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates, which would adversely affect our business and financial condition.

***Use of our product candidates could be associated with adverse side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved product or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.***

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates, whether used alone or in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product

candidates are approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials, when used alone or in combination with other approved product, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Patients in our ongoing and planned clinical trials may suffer significant adverse events or other side effects, including adverse events not observed in our preclinical studies or in previous clinical trials evaluating our product candidates. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If such significant adverse events or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Moreover, adverse developments in clinical trials conducted by others of cell therapy products or product candidates, may cause the FDA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing our technologies, either of which could materially harm our business. For example, on November 28, 2023, the FDA announced that it was investigating reports of reports of T-cell malignancies, including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA-or CD19-directed autologous CAR T cell immunotherapies, and in January 2024, the FDA required the manufacturers of certain CAR-T therapies to add boxed warnings to product labeling cautioning against the risk of T-cell malignancies. If we are able to successfully develop and obtain approval of any of our product candidates, the FDA may require such products to carry similar warnings or adopt other precautions that could adversely affect such products' commercial prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy (REMs) to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or end-to-end supply chain management systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop. Other potentially significant negative consequences associated with adverse events include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;



- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

***Interim, “topline” and preliminary data from our clinical trials and preclinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

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

Interim data from clinical trials that we may complete are further 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, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

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

***We have not successfully completed the testing of our product candidates in clinical trials and any favorable data from trials conducted by Stanford University or the NCI may not be replicated in our clinical trials.***

In December 2023, we announced the dosing of the first seven patients in our Phase 2 clinical trial of our lead product candidate, CRG-022, in patients with R/R LBCL whose disease has progressed after CD19-directed CAR T-cell therapy. We have only recently initiated our first clinical trial of CRG-022 and have not successfully completed

the test of our product candidates in clinical trials, including our lead program CRG-022. Specifically, while the CRG-022 CAR has been included in CD22 CAR T-cell products dosed in more than 120 patients in separate clinical trials conducted by Stanford University and the NCI, these trials were designed and conducted by third parties. Further, we also did not control the preclinical development of CRG-022, which was conducted by Stanford University and NCI. As a result of the foregoing, there are certain aspects of these clinical trials which could lead to our Phase 2 clinical trial producing different results. For example, it is possible that the selection of patients dosed in the Phase 1 clinical trial conducted by Stanford being different than the selection criteria we utilize in our Phase 2 clinical trial. If that were to occur, the results we receive in our Phase 2 clinical trial may be different, such as a lower complete response rate and overall response rate as well as a shorter median survival, than what was observed in the Phase 1 clinical trial conducted by Stanford University. Different results may require us to augment our clinical development plans, which could be costly, or could result in us abandoning the development of CRG-022. The occurrence of either event would harm our business.

In addition, we have changed the manufacturing process of CRG-022 in an effort to improve manufacturing yields and efficiency. These improvements are reflected in the CRG-022 being used in our potentially pivotal Phase 2 clinical trial and in December 2023, we successfully manufactured CRG-022 and dosed our first seven patients. While we have conducted comparability analysis of our CRG-022 to the CAR T therapy used in the Stanford study and concluded that the two are comparable, we cannot assure you that such comparability will result in the outcome in our Phase 2 clinical trial being consistent with the outcome observed in the Stanford University conducted Phase 1 clinical trial. In such case, additional clinical and/or CMC development work may be required to address the differences in the outcome.

If our Phase 2 clinical trial results are not consistent with the results from the Phase 1 clinical trial conducted by Stanford University, the development of CRG-022 may be adversely impacted, which could harm our business, operating results, prospects or financial condition.

Further, while we received allowance to proceed from the FDA in connection with our IND for CRG-022, which included our comprehensive package to establish the comparability of our intended commercial process to the process used for the Stanford clinical trial, we cannot assure you going forward that the FDA will agree with our claim of comparability and the sufficiency of the data to support it, or agree with our ability to reference the preclinical, manufacturing or clinical data generated by the Stanford clinical trial even if we receive a right of reference from Stanford. If so, the FDA may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate further clinical trials and/or obtain any regulatory approvals. Any of these occurrences may harm our business, financial condition and prospects.

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

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and end-to-end supply chain management of our product candidates are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets. In the U.S., we are not permitted to market our product candidates in the U.S. until we receive regulatory approval of a BLA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of biologics in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe, pure and potent or efficacious with for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if

we believe available preclinical or clinical data support the safety, purity, potency or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

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

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected treatment-related side effects may be experienced by participants in our clinical trials or by individuals using therapies similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on end-to-end supply chain management and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies;
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities.

Even if we eventually complete clinical trials and receive approval of a BLA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

***If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates or a companion diagnostic we contemplate developing with collaborators in connection with our CD22 CAR T-cell therapy, and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.***

If the FDA believes that the safe and effective use of any of our product candidates depends on an in vitro diagnostic (IVD), then it may require approval or clearance of that diagnostic as a companion diagnostic at the same time that the FDA approves our product candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such test, which would be subject regulatory approval requirements. The process of obtaining or creating such diagnostic is time-consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect. In addition, in January 2024, the FDA announced its intention to initiate the process to reclassify into Class II most IVDs that are currently regulated as Class III medical devices, including certain companion diagnostic IVDs. If such reclassification efforts occur, any companion diagnostics that are the subject of the down-classification may no longer require premarket approval, but rather may be marketed pursuant to the generally less burdensome 510(k) clearance process. However, there is no assurance that any companion diagnostic required for our development programs will benefit from the reclassification, or that the reclassification, even if it does occur, will result in a shorter timeline to development or marketing of the companion diagnostic.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains regulatory approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

***We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.***

We may in the future seek accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An

intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the biologic's clinical benefit. If such post-approval studies fail to confirm the biologic's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the biologic on an expedited basis. In addition, in December 2022, President Biden signed an omnibus appropriations bill to fund the U.S. government through fiscal year 2023. Included in the omnibus bill is the Food and Drug Omnibus Reform Act of 2022, which among other things, provided FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA seeking accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

***A Breakthrough Therapy designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive FDA approval.***

We may seek Breakthrough Therapy designations for CRG-022 and our product candidates where we believe the clinical data support such designation. A "Breakthrough Therapy" is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, where preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, increased interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as Breakthrough Therapies also receive the same benefits associated with the FDA's Fast Track designation program, including eligibility for rolling review of a submitted BLA, if the relevant criteria are met.

Although we have not applied for or received Breakthrough Therapy Designation in connection with our IND for CRG-022, Stanford University has received Breakthrough Therapy designation from the FDA for its CD22 CAR T-cell therapy candidate for, following fludarabine and cyclophosphamide, the treatment of adult patients with relapsed or refractory large B cell lymphoma after CD19-directed CAR T-cell therapy. Although Stanford University's CD22 CAR T is an earlier version of CRG-022, our CRG-022 program will not receive the benefits of this designation until and unless we obtain the rights to Stanford University's IND for the program and the FDA agrees to transfer the designation to our IND for CRG-022, or until we otherwise request and obtain such designation from the FDA with respect to our IND for CRG-022. We cannot assure you that the FDA will agree with our claim of comparability and the sufficiency of the data to support it, or agree with our ability to reference the preclinical, manufacturing or clinical data generated by the Stanford clinical trial even if we obtain a right of reference from Stanford. If the FDA disagrees, there may be limitations on the inclusion of Phase I data in the product label.

Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under standard FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification and rescind the designation, or otherwise decide that the time period required for FDA review or approval will not be reduced.

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

The ability of the FDA and foreign regulatory authorities 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 or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, during the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has resumed standard inspection operations, any resurgence of COVID-19 or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Even if we obtain FDA approval for any of our product candidates in the United States, we may never obtain approval for or commercialize such candidates in any other jurisdiction, which would limit our ability to realize their full market potential.***

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

***Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.***

For any regulatory approvals that we may receive for our product candidates, the manufacturing processes, labeling, packaging, end-to-end supply chain management, 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 ongoing compliance with cGMPs for manufacturing, as well as GCPs for any clinical trials that we may conduct. In addition, manufacturers of biological products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and other applicable standards. In addition, any regulatory approvals we may receive will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, and such approvals may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, such regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on end-to-end supply chain management or use of product, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

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

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also 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 we may not achieve or sustain profitability.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs and biologics. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be

safe, pure and potent or effective, by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs and biologics for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

***The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue.***

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are



successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop. In addition, in the event that we develop companion diagnostic tests for use with our products, once approved, such companion diagnostic tests will require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical product. Similar challenges to obtaining coverage and reimbursement applicable to pharmaceutical products will apply to companion diagnostics tests.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. 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.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

***Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain regulatory approval for and commercialize our product candidates and may affect the prices we may set.***

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may

reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered outpatient drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in place in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's Average Manufacturer Price. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for products.

Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update its guidance documents as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, even though this part of the IRA remains subject to ongoing legal challenges. The impact of the IRA on the pharmaceutical industry and our business cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

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

We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from

private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

***We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease or order, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 civil False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, 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;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and 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 nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

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

We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition and patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

## **Risks related to our dependence on third parties**

***We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.***

We are dependent on third parties to conduct our clinical trials and preclinical studies. Specifically, we rely on, and will continue to rely on, medical institutions, clinical investigators, CROs, CDMOs and consultants to conduct clinical trials and preclinical studies, in each case in accordance with trial protocols and regulatory requirements. These CROs, CDMOs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. Though we expect to carefully manage our relationships with such CROs, CDMOs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, while we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs, CDMOs and other third parties does not relieve us of our regulatory responsibilities.

In addition, we and our CROs and CDMOs are required to comply with Good Laboratory Practice (GLP) and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs, CDMOs or trial sites fail to comply with applicable GLP, GCP, cGMP or other requirements, the data generated in our preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional studies or trials before approving our marketing applications, if ever. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, CDMOs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other activities that could harm our competitive position.

In addition, our CROs and CDMOs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. 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. Switching or adding additional CROs, CDMOs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO or CDMO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs and CDMOs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We currently rely on third parties for the manufacture of our product candidates during clinical development, and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of critical reagents, raw materials and our final product candidates, or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts.***

We do not own or operate manufacturing facilities at this time. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates, lentiviral vector and related raw materials for clinical

development, as well as for commercial manufacture if any of our product candidates receives regulatory approval. The facilities used by our third-party manufacturers must be approved for the manufacture of our product candidates by the FDA, or any comparable foreign regulatory authority, pursuant to inspections that will be conducted after we submit a BLA to the FDA, or submit a comparable marketing application to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of our product candidates. If these third-party manufacturers cannot successfully manufacture material or components thereof that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities and will cause supply disruption.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture our product candidates, or if such authorities withdraw any such approval in the future, we may be required to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our financial position.

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

- an inability to initiate or complete clinical trials of our product candidates in a timely manner;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- additional inspections by regulatory authorities of third-party manufacturing facilities or our manufacturing facilities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize any product candidate, an inability to meet commercial demands.

In addition, we do not have any noncancellable long-term commitments or supply agreements with any third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our product candidates or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product candidates according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Further, while we do not have any noncancellable long-term commitments or supply agreements with third-party manufacturers, many of our agreements with such parties have liquidated damage provisions in them which require us to pay cancellation fees for any manufacturing work that we cancel but had already been scheduled or

otherwise committed to by us, as well as certain out-of-pocket expenses. Such cancellation fees could be significant and if we are required to pay them, our operational results and business may be harmed.

In addition, certain of the third parties we use for our manufacturing processes provide services that would be difficult to replace. As a result, if such parties were to increase the cost of their services, we may be required to either pay higher amounts or alternatively develop and or procure an alternative solution. If either were to occur, our results of operations and business may be harmed.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval, and any related remedial measures may be costly or time-consuming to implement. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all, which would have a material adverse impact on our financial position. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods.

***Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed within a reasonable time frame and at an acceptable cost or at all.***

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our current clinical trials and preclinical studies and intend to continue to rely on these third parties for any future clinical trials that we undertake. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our preclinical studies, clinical trials and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event a new supplier must be used. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

***We may not realize the benefits of any licensing arrangement, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.***

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates we may enter into collaborations with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development

and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. Moreover, our estimates of the potential revenue we are eligible to receive under any strategic collaborations we may enter into may include potential payments related to therapeutic programs for which our collaborators may discontinue development in the future. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

In instances where we do enter into collaborations, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs;
- the collaboration partner may experience financial difficulties;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may be required to relinquish important rights such as marketing, end-to-end supply chain management and intellectual property rights;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- we and our collaboration partner may disagree regarding the development plan for product candidates on which we are collaborating (for example, we may disagree with a collaboration partner regarding target indications or inclusion or exclusion criteria for a clinical trial); or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

### **Risks related to intellectual property**

*We depend on intellectual property licensed from third parties and we are currently party to in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our proprietary technologies and product candidates. If we breach our obligations under these agreements or if any of these agreements is terminated, or otherwise experience disruptions to our business relationships with our licensors, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business.*

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. We are a party to intellectual property license agreements and in the future, we may enter into additional license agreements. For example, with respect to developing our product candidates, we have licensed certain intellectual property from the NCI, Oxford and Stanford University. These license agreements impose, and we expect that future



license and acquisition agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under current or future intellectual property license agreements, we may be required to pay damages and the licensor may have the right to terminate the license. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop, manufacture, use and/or commercialize our product candidates or platform technologies. See the section titled “Business—Intellectual property—License agreements” for additional information regarding these key agreements.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, manufacture, use and/or commercialize the affected product candidates or platform technologies. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor’s rights.

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

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

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may also arise between us and our current and future licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology;
- rights upon termination of the license agreements;
- the scope and duration of exclusivity obligations of each party to the license agreements;
- the amount and timing of payments owed under license agreements; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

The resolution of any contractual interpretation dispute that may arise, if unfavorable to us, could have a material adverse effect on our business, financial condition, results of operations and prospects. Such resolution could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement or decrease the third party's financial or other obligations under the relevant agreement. Furthermore, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

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

Certain patents and patent applications relating to our product candidates, platform technologies or certain products used in the manufacturing of our clinical products are owned or controlled by certain of our licensors, including Stanford University, the NCI and Oxford. In some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance and defense of patent applications or patents covering technology that we license from third parties. In such circumstances, our licensors generally have rights to file, prosecute, maintain and defend the licensed patents in their name, generally with our right to comment on such filing, prosecution, maintenance and defense, with some obligation for the licensor to consider or incorporate our comments. We generally have the first right to enforce our exclusively licensed patent rights against third parties, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, including due to the impact of the COVID-19 pandemic on our licensors' business operations, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even in the circumstances where we have the right to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Furthermore, the U.S. government and/or government agencies have provided, and in the future may provide, funding or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. We rely on our licensors to ensure compliance with applicable obligations arising from such funding or assistance, such as timely reporting, an obligation associated with in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents.

***We may not be successful in obtaining or maintaining necessary rights for our product pipeline which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.***

We own or license from third parties certain intellectual property rights necessary to develop our product candidates. The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights, including to expand our product pipeline. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties.

Furthermore, other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. Our product candidates may also require specific formulations or other technology to work effectively and efficiently. These formulations or technology may be covered by intellectual property rights held by others. From time to time, in order to avoid infringing these third-party rights, we may be required to license technology from additional third parties to further develop, manufacture or commercialize our product candidates. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, 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, and as a result we may be unable to develop, manufacture or commercialize the affected product candidates, 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.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

***We may be dependent on intellectual property for which development was funded or otherwise assisted by, the U.S. government and/or government agencies, such as The National Cancer Institute, for development of our technology and product candidates. Failure to meet our own obligations to such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.***

The U.S. government and/or government agencies have provided, and in the future may provide, funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U.S. government and/or government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses, could result in the loss of significant rights and could harm our ability to commercialize licensed products and harm our competitive position, business, financial condition, results of operations and prospects. For example, the research resulting in certain of our in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology.

***Our proprietary position may depend upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.***

Composition-of-matter patents on the active pharmaceutical ingredient (API) in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. We currently have claims in our in-licensed issued U.S. patents that cover the composition-of-matter of our product candidates that expire in 2033 without taking into account any possible patent term adjustments or extensions. We are pursuing claims in our pending owned or in-licensed patent applications that cover the manufacturing, formulation or method-of-use of our product candidates. Our proprietary patent position of our product candidates after 2033 may depend upon issuance of patents from such patent applications. The claims in such patents may not prevent a competitor or other third party from using the same product candidate for a noncovered use, from using a noncovered formulation or from making the same product candidate by a noncovered process.

***If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.***

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

- if and when any patents will issue;
- whether any of our patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage, including the degree and range of protection our patents that may be issued will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether any of our intellectual property will provide any competitive advantage;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose; or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including as a result of the COVID-19 pandemic impacting our or our licensors' operations. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

Composition of matter patents for biological and pharmaceutical products 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, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents

will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label” for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement can be difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical fields can be uncertain, and evaluating the scope of such patents involves complex legal, factual and scientific analyses and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. Recent years have witnessed constant changes in policy governing the scope of claims allowable in the field of antibodies and adoptive cell therapy in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights, and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent’s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party’s pending application will issue with claims of relevant scope. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any

patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, reexaminations or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

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

***Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same

manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our products, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes and software, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.***

Some of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

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

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post-grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Furthermore, patent reform and changes to patent laws in the United States and in foreign jurisdictions add uncertainty to the possibility of challenge to our patents in the future, and could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming



and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or supply chain activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. We cannot provide any assurances that valid third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents or other intellectual property, or that we are otherwise employing their proprietary technology without authorization and may sue us. There may be third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. We are aware of certain third-party patents, including by parties such as Juno Therapeutics, Kite Pharma, the United States Department of Health and Human Services, University of Pennsylvania, and Fred Hutchinson Cancer Research Center with claims to compositions and methods that may be relevant to our product candidates. We believe that we have reasonable defenses against possible allegations of infringement, such as noninfringement or invalidity defenses. There can be no assurance that these defenses will succeed. It is also possible that patents owned by third parties of which we are aware or might become aware, but which we believe are not valid, or do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties, 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 obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates, and may claim that use of our technologies or the manufacture, use or sale of our product candidates infringes upon these patents. If any such third-party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, or if we are found to otherwise infringe a third-party's intellectual property rights, the holders of any such patents may be able to block, including by court order, our ability to develop, manufacture or commercialize the applicable product candidate unless we obtain a license under the applicable patents or other intellectual property, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even

if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

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

Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Patents are of national or regional effect, and filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. In addition, the laws of some foreign countries, particularly certain developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biotechnology products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such

disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

Competitors may infringe our patents or other intellectual property or the intellectual property of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. In addition, in an infringement proceeding or a declaratory judgment action, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim we infringe their patents or that the patent covering our product candidate is invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent, including lack of novelty, obviousness, non-enablement or insufficient written description or that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and such an outcome may limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Such a loss of patent protection could have a material adverse impact on our business. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

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

patent application related to our product candidates and other proprietary technologies we may develop or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in a series of cases, the U.S. Supreme Court held that certain claims do not present patentable subject matter (*Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (2012); *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.* (2013); *Alice Corp. v. CLS Bank International* (2014)). For example, the U.S. Supreme Court held that certain claims covering a genus of antibodies do not satisfy the enablement requirement of the Patent Act (*Amgen Inc. et al. v. Sanofi et al.* (2023)). Although we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we cannot predict how their interpretation and future decisions by Congress, the federal courts or the USPTO may impact the value of our patents and may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC over the first seven years of the court's existence and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the

life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on our business, financial condition, results of operations and prospects. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution.

A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each regulatory approval, and any patent can be extended only once, for a single product. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, or 5 years from the expiration date of the patent to be extended. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, if we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

***Our use of open source software could impose limitations on our ability to commercialize our product candidates.***

Our use of open source software could impose limitations on our ability to commercialize our product candidates. Our technology may use open source software that contains modules licensed for use from third-party authors under open source licenses. Some of the software may be provided under license arrangements that allow use of the software for research or other non-commercial purposes. As a result, in the future, as we seek to use our platform in connection with commercially available products, we may be required to license that software under different license terms, which may not be possible on commercially reasonable terms, if at all. If we are unable to license software components on terms that permit its use for commercial purposes, we may be required to replace those software components, which could result in delays, additional cost and/or additional regulatory approvals.

Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the software code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain of the open source licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of open source software, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our product candidates. We could be required to seek licenses from third parties in order to continue offering our product candidates, to re-engineer our product candidates or to discontinue the sale of our product candidates in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

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

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

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

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions.

Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential

for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

### **Risks related to ownership of our common stock**

*Our stock price has been, and is likely to continue to be highly volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.*

The trading price of our common stock has been, and is likely to continue to be, highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. 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. The trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors described in this “Risk factors” section:

- the timing, progress, costs, commencement, enrollment or results of current and future clinical trials and preclinical studies we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including, without limitation, the issuance by the FDA of a “refusal to file” letter or a request for additional information;
- changes in laws or regulations in the United States or other countries, including, but not limited to, preclinical study or clinical trial requirements for approvals;
- changes in the structure of healthcare payment systems;
- successful or negative clinical outcomes or other adverse events related to product candidates being developed by others in the oncology or cell therapy fields;
- publication of research reports about us or our industry, or cell therapy programs in particular including, but not limited to, any publications Stanford University or the NCI may make regarding the development of their CD22 programs, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any changes to our relationship with manufacturers, suppliers, collaborators or other strategic partners;
- manufacturing or supply challenges;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- variations in our results of operations or those of companies that are perceived to be similar to us;



- our cash position;
- an inability to obtain additional funding;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;
- our inability to establish collaborations, if needed;
- our ability to effectively manage our growth;
- changes in the market valuations of similar companies;
- press reports, whether or not true, about our business;
- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity markets;
- ineffectiveness of our internal controls;
- changes or developments in the global regulatory environment;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement or expectation of additional financing efforts;
- expiration of market stand-off or lock-up agreements;
- general political and economic conditions;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the trading price of our common stock, regardless of our actual operating performance. If the trading price of our common stock does not exceed the initial public offering price, you may not realize any return on, and may lose some or all of, your investment.

***Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- timing and variations in the level of expense related to the current or future development of our programs;
- stock-based compensation estimates;
- our ability to enroll patients in clinical trials and timing and status of enrollment for our clinical trials;
- timing and results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from products that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;

- any delays in regulatory review or approval of our product candidates;
- our execution of any collaboration, licensing or similar arrangements and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any product candidates we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates, which may be difficult to predict;
- the timing and cost to establish a sales, marketing and supply chain infrastructure to commercialize any products for which we may obtain regulatory approval and intend to commercialize on our own or jointly with current or future collaborators;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with any of our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies;
- regulatory developments affecting current or future product candidates or those of our competitors;
- impact from the COVID-19 pandemic on us or third parties with which we engage; and
- changes in general global market, political and economic conditions.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In preparing the financial statements as of and for the year ended December 31, 2022, management has identified it had not fully maintained components of the COSO framework, a system for establishing internal controls, which constituted material weaknesses. Specifically, the control deficiencies related to: (i) an insufficient complement of personnel with an appropriate level of technical knowledge to create the proper environment for effective internal control over financial reporting, (ii) the lack of an effective risk assessment process, (iii) the lack of formalized processes and control activities to support the appropriate segregation of duties over the review of account reconciliations and journal entries and (iv) the lack of monitoring and communication of control processes and relevant accounting policies and procedures.

These material weaknesses resulted in adjustments to the financial statements.

To remediate these material weaknesses, we are in the process of implementing measures designed to review and document financial processes and controls, formalizing policies and procedures to improve our internal controls over financial reporting, as well as hiring of qualified resources to the finance department, including supervisory roles. As of December 31, 2023, these material weaknesses have not yet been remediated.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

***An active, liquid trading market for our common stock may not be maintained.***

We can provide no assurance that we will be able to maintain an active trading market for our common stock. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products or technologies by using our common stock as consideration.

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

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates own approximately 74.8% of our outstanding voting stock as of December 31, 2023. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

Our common stock price could decline as a result of sales of a large number of shares of common stock in the public market or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

The lock-up agreements entered into in connection with our IPO will expire at the close of business on May 7, 2024. J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC, in their sole discretion, may permit our equity holders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, the shares of common stock will be eligible for sale in the public market. Approximately 38.4% of these additional shares are owned by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act. In addition, approximately 7.6 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline. In addition, the holders of approximately 18.9 million shares, or 45.9% of our total outstanding common, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

In addition, in the future, we may issue additional shares of common stock, or other equity or convertible debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value of our common stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

***Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change in control of

our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of the board of directors will be elected at one time;
- authorize our board of directors to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our amended bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66-2/3% of all outstanding shares of our voting stock;
- require the approval of not less than 66-2/3% of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and
- the jurisdictions in which certain stockholder litigation may be brought.

As a Delaware corporation, we will be subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of our company.

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.***

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision 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, which could harm our business, financial condition and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and we may not achieve profitability. As of December 31, 2023, we had U.S. federal and state net operating loss carryforwards (NOLs) of \$10.8 million and \$2.3 million, respectively. Our federal NOL carryforwards of \$10.8 million carry forward indefinitely. The state NOL carryforwards of \$2.3 million begin to expire in 2040. In addition, as of December 31, 2023, we have U.S. federal and state research and development tax credits of \$2.3 million and \$1.9 million, respectively. The federal research and development tax credits of \$2.3 million begin to expire in 2042. The state research and development tax credits of \$1.9 million carry forward indefinitely.

Changes in tax laws or regulations may adversely impact our ability to utilize all, or any, of our NOL carryforwards. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the TCJA), significantly revised the Internal Revenue Code of 1986 (the Code), as amended. Future guidance from the Internal Revenue Service and other tax authorities with respect to the TCJA may affect us, and certain aspects of the TCJA could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) modified certain provisions of the TCJA. Under the TCJA, as modified by the CARES Act, unused losses generated in taxable years ending after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the to the TCJA or the CARES Act.

Under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes as a result of our acquisitions of assets and/or subsequent shifts in our stock ownership (some of which are outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits. As of December 31, 2023, we have a valuation allowance for the full amount of our net deferred tax assets as the realization of the net deferred tax assets is not determined to be more likely than not.

**General Risk Factors**

***If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.***

The trading market for our common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more of these analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly

publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

***We are an “emerging growth company” as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:***

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the completion of our initial public offering. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than \$1.235 billion in annual revenue;
- the date we qualify as a “large accelerated filer,” with at least \$700.0 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, if we are a smaller reporting company with less than \$100.0 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (Section 404).

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies and smaller reporting companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the trading price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for any new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

***The requirements of being a public company may strain our resources, result in more litigation and divert management’s attention.***

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The

Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to continue to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are 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. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this Annual Report on Form 10-K and in future filings required under the Exchange Act, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

***Failure to comply with governmental laws and regulations could harm our business.***

Our business is subject to regulation by various federal, state, local and foreign governments. Noncompliance with applicable regulations or requirements could subject us to investigations, sanctions, enforcement actions, disgorgement of profits, fines, damages, civil and criminal penalties, injunctions or other collateral consequences. If any governmental sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, operating results, and financial condition could be materially adversely affected. In addition, responding to any action will likely result in a significant diversion of management's attention and resources and an increase in professional fees. Enforcement actions and sanctions could harm our business, reputation, operating results and financial condition.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.



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

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that future deterioration in credit and financial markets and confidence in economic conditions will not occur. 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 proper and effective internal controls over financial reporting, our ability to produce accurate and timely financial statements could be impaired.***

Pursuant to Section 404 of Sarbanes-Oxley and the related rules of the SEC, our management will be required to report on the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2024. When we lose our status as an “emerging growth company” and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if we and/or our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial statements, the trading price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***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 a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion

of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***If our estimates or judgments relating to our critical accounting policies prove to be incorrect or financial reporting standards or interpretations change, our results of operations could be adversely affected.***

The preparation of financial statements in conformity with generally accepted accounting principles in the United States (U.S. GAAP), requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, as provided in “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical accounting policies and estimates.” The results of these estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our financial statements include but are not limited to stock-based compensation and evaluation of acquisitions of assets and other similar transactions as well as clinical trial accruals. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock.

Additionally, we regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards and changes in their interpretation, we might be required to change our accounting policies, alter our operational policies and implement new or enhance existing systems so that they reflect new or amended financial reporting standards, or we may be required to restate our audited or unaudited financial statements and related notes. Such changes to existing standards or changes in their interpretation may also have an adverse effect on our reputation, business, financial position and profit.

***We could be subject to changes in tax rates, the adoption of new tax legislation or could otherwise have exposure to additional tax liabilities, which could harm our business.***

Changes to tax laws or regulations in the jurisdictions in which we operate, or in the interpretation of such laws or regulations, could significantly increase our effective tax rate, and otherwise have a material adverse effect on our financial condition. In addition, other factors or events, including business combinations and investment transactions, changes in stock-based compensation, changes in the valuation of our deferred tax assets and liabilities, adjustments to taxes upon finalization of various tax returns or as a result of deficiencies asserted by taxing authorities, increases in expenses not deductible for tax purposes, changes in available tax credits, changes in transfer pricing methodologies, other changes in the apportionment of our income and other activities among tax jurisdictions and changes in tax rates, could also increase our effective tax rate. Our tax filings are subject to review or audit by the U.S. Internal Revenue Service (the IRS) and state, local and foreign taxing authorities. We may also be liable for taxes in connection with businesses we acquire. Our determinations are not binding on the IRS or any other taxing authorities, and accordingly the final determination in an audit or other proceeding may be materially different than the treatment reflected in our tax provisions, accruals and returns. An assessment of additional taxes because of an audit could harm our business.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that individuals working for or collaborating with us do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information proprietary to these third parties or our employees’ former employers, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. We may be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants, advisors or other third parties, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in

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

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the trading price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition. Additionally, the dramatic 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.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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

None.

**Item 1C. Cybersecurity.**

*Cybersecurity Risk Management and Strategy*

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST). This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- overall risk assessment;
- a technology team leveraging a third-party Security Operations Center (SOC) partner to monitor, manage and respond to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees and regular phishing campaigns;
- a cybersecurity incident response policy that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors that have access to our critical systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled “Risk Factors—Risks related to our business—Our information technology systems, or those used by our third-party contract research organizations or other contractors or consultants, may fail or suffer security breaches.”

#### *Cybersecurity Governance*

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (Committee) oversight of cybersecurity and other information technology risks. The Committee oversees management’s implementation of our cybersecurity risk management program.

The Committee receives quarterly updates from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program.

Our management team, including the Vice President of IT and the Senior Vice President of Finance, General & Administrative, is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management team’s experience includes over 25 years of experience leading technology management functions within biotech companies as well as interacting with the Board.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment.

## **Item 2. Properties.**

Our principal office is currently located at 1900 Alameda Las Pulgas, Suite 350, San Mateo, California, where we lease an approximately 31,117 square foot facility, used as laboratory, research and office space which expires in November 2024. In December 2023, our lease of 99,557 square foot of laboratory and office space at 835 Industrial Road, San Carlos, California commenced and the lease expires in May 2031. We intend to move our principal office to the new leased location in San Carlos. See Note 5 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information. We believe that our current facilities are suitable and adequate to meet our current needs.

**Item 3. Legal Proceedings.**

We are not currently a party to any material legal proceedings. From time to time, we may, however, in the ordinary course of business become involved in legal proceedings. Regardless of outcome, litigation could have a material adverse effect on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

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

#### **Market Information**

Our common stock is traded on the NASDAQ Global Market under the symbol “CRGX.”

#### **Holders of Record**

As of March 13, 2024, there were 44 holders of record of our common stock. The actual number of holders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

#### **Dividend Policy**

We have never declared or paid cash dividends on our capital stock. We do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings, if any, will be used for the operation and growth of our business. Any future determination to declare cash dividends would be subject to the discretion of our board of directors and would depend upon various factors, including our results of operations, financial condition and capital requirements, restrictions that may be imposed by applicable law and our contracts and other factors deemed relevant by our board of directors.

#### **Equity Compensation Plan Information**

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

#### **Use of Proceeds from our Initial Public Offering**

On November 9, 2023, our registration statement on Form S-1 (File No. 333-275113) (the Prospectus) relating to our initial public offering (IPO) became effective pursuant to which we issued and sold 21,262,181 shares of our common stock at a public offering price of \$15.00 per share. We received net proceeds of \$291.0 million, after deducting the underwriting discounts, commissions and offering expenses. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. J.P. Morgan Securities LLC, Jefferies LLC, Cowen and Company, LLC and Truist Securities, Inc. who acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from the IPO from that described in the Prospectus.

#### **Recent Sales of Unregistered Securities**

In October 2023, we issued and sold an aggregate of 6,341,150 shares of our Series A-1 redeemable convertible preferred stock, par value \$0.001 per share, to the purchasers listed on Exhibit A of the Series A Preferred Stock Purchase Agreement at a purchase price of \$13.57 per share, for net proceeds of approximately \$86.0 million.

#### **Issuer Repurchases of Equity Securities**

During the quarter ended December 31, 2023, we did not repurchase any equity securities.

#### **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 together with the audited financial statements and related notes included 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 performance that involves 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 discussed in the forward-looking statements as a result of several factors including those set forth in the section titled “Risk Factors.” See also the section titled “Special Note Regarding Forward-Looking Statements”.

**Overview**

We are a clinical-stage biotechnology company uniquely positioned to advance next generation, potentially curative cell therapies for cancer patients. Our programs, platform technologies, and manufacturing strategy are designed to directly address the limitations of approved chimeric antigen receptor (CAR) T-cell therapies. A CAR is a protein that has been engineered to modify T cells so they can recognize and destroy cancer cells. We believe the limitations of these therapies include limited durability of effect, safety concerns and unreliable supply. Our lead program, CRG-022, an autologous (derived from a patient’s cells) CD22 chimeric antigen receptor (CAR) T-cell product candidate, the underlying CAR of which we exclusively licensed, is being studied by Stanford University (Stanford) in a Phase 1 clinical trial in patients with large B-cell lymphoma (LBCL) whose disease relapsed or was refractory (R/R) to CD19 CAR T-cell therapy. On the basis of the results from the clinical trial, we are evaluating CRG-022 in a potentially pivotal Phase 2 clinical trial in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. We also plan to evaluate CRG-022 in patients at earlier stages of disease, including LBCL and other hematologic malignancies. Beyond our lead program, we are leveraging our proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multiple transgene therapeutic “cargo” designed to enhance CAR T-cell persistence, as well as to help safeguard against tumor resistance and T-cell exhaustion. Our founders are pioneers and world-class experts in CAR T-cell therapy, and our team has significant experience and success developing, manufacturing, launching and commercializing oncology and cell therapy products. We aim to become a fully integrated, leading cell therapy company. Together, we are united in our mission to outsmart cancer and deliver more cures for patients.

Program	Target(s)	Indication(s)	Stage of Development					Commercial rights
			Discovery	IND-enabling	Phase 1	Phase 2	Phase 3	
CRG-022 (CAR T)	CD22	R/R LBCL - post CD19 CAR T						
		LBCL - CAR T naïve <sup>(1)</sup>						
		Pediatric B-ALL						
CRG-023 (tri-specific CAR T with CD2 co-stimulation)	CD19 CD20 CD22	B-cell malignancies						

<sup>(1)</sup> Based on data from the Phase 1 clinical trial conducted by Stanford and pending data from our ongoing Phase 2 clinical trial in R/R LBCL – post CD19 CAR T, we intend are in discussions with the FDA on the initiation of a Phase 2 program in LBCL – CAR T naïve without completing earlier clinical trials in LBCL – CAR T-naïve patients.

On November 14, 2023, we closed our initial public offering (IPO) pursuant to which we sold 18,750,000 shares of our common stock at a price to the public of \$15.00 per share and on November 21, 2023, we issued and sold 2,512,181 additional shares of our common stock to the underwriters of the IPO pursuant to the partial exercise of

their option to purchase additional shares. We received net proceeds of \$291.0 million after deducting underwriting discounts, commissions and offering expenses.

We have incurred significant operating losses and negative cash flows since our inception. Since our founding, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, establishing licensing arrangements, building our proprietary platform technologies, discovering our product candidates, establishing our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and related raw materials, and providing general and administrative support for these operations.

Our net loss was \$98.1 million and \$41.0 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$145.1 million and cash and cash equivalents of \$405.7 million. During the year ended December 31, 2023, we raised aggregate net cash proceeds of \$494.4 million from our IPO, the sale and issuance of our redeemable convertible preferred stock and convertible notes. Based on our current operating plans, we estimate that our existing cash and cash equivalents will be sufficient to meet our working capital and capital expenditures through 2025. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

We expect to continue to incur significant and increasing net operating losses for the foreseeable future as we:

- advance our product candidates through clinical and preclinical development;
- seek regulatory approval, prepare for and, if approved, proceed to commercialization of our product candidates;
- continue our research and development efforts and expand our pipeline of product candidates;
- attract, hire and retain additional personnel;
- maintain, expand and protect our intellectual property portfolio;
- operate as a public company;
- implement operational, financial and management information systems;
- make royalty, milestone or other payments under current, and any future, license or collaboration agreements;
- potentially seek to identify, acquire or in-license new technologies or product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- potentially experience any delays, challenges, or other issues associated with the clinical development of our product candidates, including with respect to our regulatory strategies; and
- develop manufacturing processes and methods and establish manufacturing capacity to supply for clinical trials in our pipeline and eventual for commercialization.

Our net losses may fluctuate significantly from period to period, depending upon the timing of our expenditures on other research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued research and development and other current liabilities.

To date, we have funded our operations primarily with the proceeds from the sale and issuance of our convertible preferred stock and convertible notes as well as the sale and issuance of our common stock in our IPO. We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our



product candidates, we will need to continue to raise substantial additional capital. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to fund our operations through public or private equity offerings or debt financings, credit or loan facilities, potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions, or a combination of one or more of these funding sources. If we are unable to obtain adequate funding as and when needed, or on attractive terms, we could be required to significantly delay, reduce or eliminate some or all of our research and development activities, product portfolio expansion or commercialization efforts, out-license intellectual property rights to our product candidates, sell unsecured assets, or scale back or terminate our pursuit of new strategic arrangements and transactions, or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all. See the subsection titled “—*Liquidity and capital resources*” below.

We utilize third-party contract development and manufacturing organizations (CDMOs), to manufacture and supply our preclinical and clinical materials during the development of our product candidates, as well as third-party contract research organizations (CROs) to conduct our clinical trials and preclinical studies. We expect to use similar contract resources for the commercialization of our products, at least until our resources and operations are at a scale that justifies investment in internal manufacturing capabilities. The terms and conditions for each of the CDMOs are defined in the respective manufacturing and supply agreements.

## **Components of operating results**

### ***Operating expenses***

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

### ***Research and development expenses***

Our research and development expenses consist of direct costs, including manufacturing and technical operations, preclinical and clinical fees paid to clinical research organizations, supplies, health authority filings, technology licenses and in-process research and development (IPR&D) assets as well as indirect costs consisting of employee-related costs and allocated facilities and other operating costs.

We expense all research and development costs in the periods in which such costs are incurred. Since we are engaged in multiple research and development programs at any one time, we track our direct costs by the stage of program, clinical or preclinical. Our indirect costs are not directly tied to any one program and are deployed across multiple programs, and as such, we do not track indirect costs on a specific program basis.

We cannot reasonably determine the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. We expect that our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates as our product candidates advance into later stages of development, as we begin to conduct clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, as we expand our product pipeline, as we maintain, expand, protect and enforce our intellectual property portfolio, and as we incur expenses associated with hiring additional personnel to support our research and development efforts.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. Our research and development expenses may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
- the phases of development of our product candidates;
- the progress and results of our research and development activities;

- per subject trial costs;
- the number of trials required for regulatory approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- length of time required to enroll eligible subjects and initiate clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing of our product candidates;
- the timing of licensing milestone payments related to development, regulatory and commercial events;
- manufacturing success with patient materials;
- the receipt of regulatory approvals from applicable regulatory authorities;
- mitigation/responses to potential health authority questions, inspections;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the hiring and retention of research and development personnel;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights; and
- the extent to which we establish collaboration, licensing or similar arrangements and the performance of any related third parties.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

#### *General and administrative expenses*

Our general and administrative expenses consist primarily of employee-related costs and expenses for outside services, including legal, human resources, audit, and accounting services, as well as facilities and other operating costs not included in research and development expenses. We expect that our general and administrative expenses will increase for the foreseeable future to support our expanding headcount and operations, and as we advance our product candidates through clinical development. We also expect to incur additional costs associated with operating as a public company, including increased expenses related to legal, audit, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, investor and public relations costs, and other administrative and professional services.

#### *Interest expense*

Interest expense primarily consists of accrued interest, amortization of debt discounts and issuance costs related to our convertible notes.

***Net change in fair value of redeemable convertible preferred stock tranche obligations***

The net change in fair value of redeemable convertible preferred stock tranche obligations consists of measurement gains or losses recorded on subsequent remeasurement of the redeemable convertible preferred stock tranche asset and liability related to our Series A-1 redeemable convertible preferred stock. We remeasured the fair value of the redeemable convertible preferred stock tranche asset until its settlement in July 2023 upon issuance of the second tranche of Series A-1 redeemable convertible preferred stock. We remeasured the fair value of the redeemable convertible preferred stock tranche liability until its settlement in October 2023 upon issuance of the third tranche of Series A-1 redeemable convertible preferred stock.

***Change in fair value of derivative liabilities***

The change in fair value of derivative liabilities consists of measurement losses recorded on subsequent remeasurement of derivative liabilities related to our convertible notes. We remeasured the fair value of the derivative liabilities until the underlying convertible notes were settled through conversion in February 2023.

***Loss on extinguishment of convertible notes***

The loss on extinguishment of convertible notes consists of the loss realized upon conversion of our convertible notes into Series A-2 redeemable convertible preferred stock in February 2023.

***Other income (expense), net***

Other income (expense), net consists primarily of federal research and development tax credits and interest income earned on our cash and cash equivalents.

**Results of operations**

***Comparison of the years ended December 31, 2023 and 2022***

Our results of operations for each of the periods indicated are summarized in the table below (in thousands):

	Year ended December 31,		Change
	2023	2022	
Operating expenses:			
Research and development	\$ 75,791	\$ 29,373	\$ 46,418
General and administrative	20,919	5,398	15,521
Total operating expenses	96,710	34,771	61,939
Loss from operations	(96,710)	(34,771)	(61,939)
Interest expense	(1,604)	(4,942)	3,338
Net change in fair value of redeemable convertible preferred stock tranche obligations	(8,783)	—	(8,783)
Change in fair value of derivative liabilities	6,453	(1,216)	7,669
Loss on extinguishment of convertible notes	(2,316)	—	(2,316)
Other income (expense), net	4,813	(22)	4,835
Net loss and comprehensive loss	<u>\$ (98,147)</u>	<u>\$ (40,951)</u>	<u>\$ (57,196)</u>

**Research and development expenses**

	Year ended December 31,		Change
	2023	2022	
	(in thousands)		
Direct costs:			
Manufacturing and technical operations	\$ 33,527	\$ 13,346	\$ 20,181
Preclinical and clinical	7,938	1,053	6,885
Consultants and other outside services	4,257	2,656	1,601
License fees	1,510	923	587
Indirect costs:			
Employee-related costs	20,934	9,118	11,816
Facilities and other operating costs	7,625	2,277	5,348
Total research and development expenses	<u>\$ 75,791</u>	<u>\$ 29,373</u>	<u>\$ 46,418</u>

Research and development expenses were \$75.8 million and \$29.4 million for the years ended December 31, 2023 and 2022, respectively. The \$46.4 million increase in research and development expenses during this period was primarily due to:

- \$20.2 million increase in manufacturing and technical operations costs, as well as increases in preclinical and clinical costs of \$6.9 million and consultants and other outside services costs of \$1.6 million, primarily related to the continued development of CRG-022 as we initiated our Phase 2 clinical trial in the third quarter of 2023;
- \$0.6 million increase in license fees primarily related to upfront fees accrued upon entering into the 2023 NCI License and fees incurred related to achievement of certain milestones;
- \$11.8 million increase in employee-related costs due to increased headcount on our research and development teams to support our development efforts, including a \$1.3 million increase in stock-based compensation expense for research and development employees;
- \$5.3 million increase in facilities and other operating costs primarily related to our new facility leases, depreciation expense related to lab equipment acquired and put into use in 2023 and increased allocated overhead as a result of our continued growth.

**General and administrative expenses**

	Year ended December 31,		Change
	2023	2022	
	(in thousands)		
Outside services	\$ 9,737	\$ 2,523	\$ 7,214
Employee-related costs	9,270	2,563	6,707
Facilities and other operating costs	1,912	312	1,600
Total general and administrative expenses	<u>\$ 20,919</u>	<u>\$ 5,398</u>	<u>\$ 15,521</u>

General and administrative expenses were \$20.9 million and \$5.4 million for the years ended December 31, 2023 and 2022, respectively. The \$15.5 million increase in general and administrative expenses during this period was primarily due to:

- \$7.2 million increase in outside services costs related to legal, accounting and audit costs, as well as an increase in outsourced human resource services;
- \$6.7 million increase in employee-related costs due to higher headcount in our finance and administrative personnel, including a \$1.8 million increase in stock-based compensation expense for general and administrative employees;
- \$1.6 million increase in facilities and other operating costs primarily related to our facility leases entered into in 2023 and software licenses fees incurred in 2023.

### ***Interest expense***

Interest expense decreased by \$3.3 million to \$1.6 million in 2023 compared to \$4.9 million in 2022. The decrease was attributable to the conversion of our convertible notes into shares of our Series A-2 redeemable convertible preferred stock in February 2023.

### ***Net change in fair value of redeemable convertible preferred stock tranche obligations***

The net change in fair value of redeemable convertible preferred stock tranche obligations related to our Series A Agreement executed in February 2023 was a net loss of \$8.8 million in the 2023 due an increase in the fair value of the tranche obligation liability of \$8.9 million settled in October 2023, partially offset by the increase in the fair value of the tranche obligation asset of \$0.1 million settled in July 2023 due to the change in the fair value of the underlying shares of our Series A-1 redeemable convertible preferred stock.

### ***Change in fair value of derivative liabilities***

The change in fair value of derivative liabilities associated with our convertible notes was a gain of \$6.5 million in 2023 compared to a loss of \$1.2 million in 2022. This change was primarily due to a decrease in the expected term of the triggering event as a result of the conversion of the convertible notes into shares of our Series A-2 redeemable convertible preferred stock in February 2023, which decreased the fair value of the embedded derivatives.

### ***Loss on extinguishment of convertible notes***

The loss on extinguishment of convertible notes was \$2.3 million in 2023. In February 2023, the convertible notes were converted into shares of our Series A-2 redeemable convertible preferred stock at a conversion price of \$10.18 per share, which exceeded the carrying value of the convertible notes and embedded derivative liabilities at the time, and resulted in a loss upon extinguishment.

### ***Other income (expense), net***

Other income increased by \$4.8 million in 2023 compared to other expense of \$22,000 in 2022 primarily due to higher interest earnings as a result of increasing interest rates on our higher cash and cash equivalents balances in 2023 from proceeds of our IPO, the sale and issuance of our redeemable convertible preferred stock and convertible notes.

### ***Liquidity and capital resources***

Since our inception, we have funded our operations primarily with the proceeds from the sale and issuance of common stock from our IPO, sale and issuance of convertible preferred stock and convertible notes. During the year ended December 31, 2023, we raised aggregate net cash proceeds of \$494.4 million from our IPO, as well as from the sale and issuance of our redeemable convertible preferred stock and convertible notes. To date, we have incurred significant losses and negative cash flows from operations. As of December 31, 2023, we had available cash and cash equivalents of \$405.7 million which are available to fund operations, and an accumulated deficit of \$145.1 million.

We expect to continue to incur significant operating losses in the foreseeable future to support our planned continued development of one or more of our product candidates. We estimate that our existing cash and cash equivalents as of December 31, 2023 will be sufficient to meet our working capital and capital expenditure needs through 2025. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

### ***Convertible notes***

In April and October 2022, we executed convertible note purchase agreements for total gross proceeds of \$25.0 million and \$12.0 million, respectively. Each note purchase agreement included three separate tranches of funding, one upon execution of the agreement and an additional two tranches upon achievement of certain milestones. We issued the three tranches under the April 2022 note purchase agreement in April, August and October 2022 for

aggregate net proceeds of \$19.9 million. We issued the first and second tranches under the October 2022 note purchase agreement in October and December 2022, respectively, for aggregate net proceeds of \$8.5 million, and the third tranche in January 2023 for net proceeds of \$3.5 million. The convertible notes issued pursuant to the note purchase agreement bore interest at 6.0% per annum and were issued with maturity dates of April 2023 and October 2023. In February 2023, concurrently with our Series A redeemable convertible preferred stock financing, the convertible notes issued pursuant to the note purchase agreement were converted into shares of our Series A-2 redeemable convertible preferred stock at a conversion price of \$10.18 per share. The notes automatically converted into 3,229,851 shares of our Series A-2 redeemable convertible preferred stock in February 2023 when we completed the initial closing of the sale of our Series A-1 redeemable convertible preferred stock.

### ***Series A-1 redeemable convertible preferred stock***

In February 2023, we executed the Series A Preferred Stock Purchase Agreement (Series A Agreement) and issued and sold 5,072,919 shares of our Series A-1 redeemable convertible preferred stock for aggregate net proceeds of \$68.1 million as part of the initial closing. Our outstanding convertible notes were also converted into 3,229,851 shares of our Series A-2 redeemable convertible preferred stock. The Series A Agreement included two additional tranche closings for 3,381,941 shares and 6,341,150 shares, respectively, at a purchase price of \$13.57 per share. We completed the second tranche closing in July 2023 for net proceeds of \$45.8 million and the third tranche closing in October 2023 for net proceeds of \$86.0 million.

### ***Future funding requirements***

Because of the numerous risks and uncertainties associated with research, development, manufacturing, supply and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching, developing and manufacturing our product candidates or any future product candidates, and conducting preclinical and clinical studies;
- manufacturing success;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of any future product candidates and any products we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the expenses needed to attract and retain skilled personnel;
- the costs of operating as a public company;
- the effect of macroeconomic trends including inflation and rising interest rates;
- addressing any potential supply chain interruptions or delays, including those related to the COVID-19 pandemic; and
- the timing, receipt and amount of sales of any future approved or cleared products, if any.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise substantial additional capital. Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating

expenses and capital expenditure requirements through at least the next 12 months following the issuance of our audited financial statements. However, until such time as we can generate significant product revenue, if ever, we expect to fund our operations through public or private equity offerings or debt financings, creditor loan facilities, potentially other capital sources, such as collaborations or licensing arrangements with third parties or other strategic transactions, or a combination of one or more of these funding sources. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect to continue to expend significant resources for the foreseeable future.

If we raise additional capital through debt or preferred equity financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments, or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, license agreements, strategic transactions or other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. If we are unable to obtain adequate funding as and when needed, or on attractive terms, we could be required to significantly delay, reduce or eliminate some or all of our research and development activities, product portfolio expansion or commercialization efforts, out-license intellectual property rights to our product candidates, sell unsecured assets, or scale back or terminate our pursuit of new strategic arrangements and transactions, or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish these plans and secure sources of financing and ultimately attain profitable operations.

### **Cash flows**

Our cash flows for each of the periods indicated are summarized in the table below (in thousands):

	Year ended December 31,	
	2023	2022
Cash used in operating activities	\$ (81,164)	\$ (29,072)
Cash used in investing activities	(8,992)	(3,282)
Cash provided by financing activities	494,583	34,185
Net increase in cash, cash equivalents, and restricted cash	<u>\$ 404,427</u>	<u>\$ 1,831</u>

### **Operating activities**

Cash used in operating activities of \$81.2 million for 2023 was primarily attributable to our net loss of \$98.1 million, partially offset by \$14.7 million in non-cash adjustments and a \$2.2 million decrease in our working capital. Non-cash adjustments consisted primarily of \$8.8 million from the net change in fair value of tranche obligations related to our Series A-1 redeemable convertible preferred stock, \$3.3 million in stock-based compensation, \$2.3 million loss on extinguishment related to an amendment and conversion of our outstanding convertible notes into shares of our Series A-2 redeemable preferred stock in February 2023, \$2.2 million in amortization of right-of-use assets, \$1.6 million in noncash interest expense primarily related to additional issuances of our convertible notes, \$1.5 million in depreciation primarily related to the purchases of equipment for research and development activities, \$1.5 million in acquisition of in-process research and development primarily related to upfront fees accrued upon entering into the 2023 NCI License and fees incurred related to achievement of certain milestones, partially offset by a \$6.5 million gain from the change in fair value of derivative liabilities related to our convertible notes. The \$2.2 million decrease in working capital is primarily due to a \$9.2 million increase in accounts payable, accrued clinical and research and development expenses, and accrued expenses and other current liabilities driven by increased research and development expenses mainly related to manufacturing and technical operations, preclinical and clinical and employee-related expenses, partially offset by a \$3.6 million increase in other assets primarily related to a deposit paid for clinical trial services, a \$1.8 million decrease in operating lease liabilities and a \$1.6 million increase in prepaid expenses and other current assets.

Cash used in operating activities of \$29.1 million for 2022 was primarily attributable to our net loss of \$41.0 million, partially offset by \$8.9 million in non-cash adjustments and a \$3.0 million decrease in our working capital. Non-cash adjustments consisted primarily of \$4.9 million in noncash interest expense and \$1.2 million in change in fair value of derivative liabilities related to our convertible notes, \$1.1 million in amortization of right-of-use asset, \$1.0 million in acquisition of in-process research and development primarily related to upfront fees incurred upon entering into the 2022 NCI License, the Oxford Agreement and the Stanford License, \$0.4 million in depreciation primarily related to the purchases of equipment for research and development activities and \$0.3 million in stock-based compensation. The \$3.0 million decrease in working capital was primarily due to a \$6.3 million increase in accounts payable, accrued clinical and research and development expenses, accrued expenses and other current liabilities driven by increased research and development expenses, including manufacturing and technical operations spending and accrued compensation and benefits driven by increased headcount, partially offset by a \$1.9 million increase in prepaid expenses and other current assets primarily related to upfront payments for manufacturing and technical operations and research services, a \$1.1 million decrease in operating lease liability and a \$0.3 million increase in other non-current assets related to deposits paid for our operating lease.

#### *Investing activities*

Cash used in investing activities of \$9.0 million for 2023 consisted of \$8.3 million in purchases of equipment for our research and development activities and \$0.7 million from the purchase of in-process research and development comprised of fees paid related to our license agreements.

Cash used in investing activities of \$3.3 million 2022 consisted of \$2.7 million in purchases of equipment for our research and development activities and \$0.6 million from the purchase of in process research and development comprised of upfront fees paid upon entering into the 2022 NCI License, the Oxford Agreement and the Stanford License.

#### *Financing activities*

Cash provided by financing activities of \$494.6 million for 2023 primarily consisted of \$291.1 million in net proceeds from our IPO, net of offering costs, \$199.9 million in proceeds from issuance of Series A-1 redeemable convertible preferred stock and \$3.5 million in net proceeds from issuance of convertible notes payable, of which \$2.2 million was from related parties.

Cash provided by financing activities of \$34.2 million for 2022 consisted of \$28.5 million in net proceeds from issuance of convertible notes, of which \$15.9 million was from related parties, \$5.5 million in net proceeds from issuance and sale of shares of our Series Seed convertible preferred stock, and \$0.2 million from the issuance and sale of restricted stock awards.

#### **Off-balance sheet arrangements**

We currently do not have, and did not have during the periods presented, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

#### **Contractual obligations and commitments**

##### ***Leases***

We have entered into lease arrangements for facilities, which comprise of office and laboratory space, through March 31, 2031. As of December 31, 2023, our total fixed lease payment obligations outstanding are \$48.1 million of which \$3.0 million is payable within 12 months.



### ***License agreements***

Our contractual obligations are expected to affect our liquidity and cash flows in future periods. Under our license agreements with our research institution partners, we are required to make payments upon successful completion and achievement of certain milestones as well as royalty payments upon sales of products covered by such licenses. The payment obligations under the license fees are recorded in accrued liabilities as such payments are not contingent on future events. The remaining payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, clinical, regulatory, and commercial milestones. To the extent that the timing of these future milestone payments is not known, we have not included these fees in our balance sheets as of December 31, 2023. For a more detailed description of these agreements, see Note 10 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

### **Critical accounting policies and significant judgments and estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are described in Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operations.

### ***Research and development expenses and accruals***

We record research and development expenses to operations as incurred. Research and development expenses represent costs incurred by us for the discovery and development of our product candidates and the development of our technology and include employee salaries, benefits and stock-based compensation, third-party research and development expenses, including contract manufacturing and technical operations, contract clinical and preclinical research services, consulting expenses, laboratory supplies, and certain allocated expenses, as well as amounts incurred under license agreements.

As part of preparing our financial statements, we are required to estimate and accrue expenses. We estimate manufacturing and technical operation costs, preclinical study and clinical trial and other research and development expenses based on the services performed, pursuant to contracts with research institutions and third-party service providers that conduct and manage manufacturing and technical operations, preclinical studies and clinical trials and research services on our behalf. We record the costs of research and development activities based upon the estimated services provided but not yet invoiced and include these costs in accrued expenses and other current liabilities in our balance sheets and in research and development expense in our statements of operations. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from external third-party service providers. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than our estimates. Contingent milestone payments, if any, are expensed when the milestone results are probable and estimable, which is generally upon the achievement of the milestone.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services provided and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that may be used to conduct and manage clinical trials on our behalf. A significant portion of our operating expenses is related to development of the manufacturing process and control system, cGMP manufacturing of critical reagents and final products at CDMOs and additional supply chain related activities. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

### ***Derivative liabilities***

Our convertible notes contain certain embedded redemption features that are not clearly and closely related to the debt host instruments. These features are bifurcated from the host instruments and recognized as derivative liabilities recorded at fair value on the date of issuance in accordance with Accounting Standards Codification (ASC) 815-15, *Derivatives and Hedging—Embedded Derivatives*. The fair value of the derivative liabilities was estimated using a “with-and-without” method which involves valuing the whole instrument on an as-is basis and then valuing the instrument without the embedded derivative. The difference between the entire instrument with the embedded derivatives compared to the instrument without the embedded derivatives is the fair value of the derivative liabilities. The estimated probability and timing of underlying events triggering the exercisability of the put option and conversion features contained within the convertible notes, forecasted cash flows and the discount rate were significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative. The derivative liabilities were remeasured to fair value at each reporting period until their extinguishment in February 2023, with changes in the fair value recorded as a change in fair value of derivative liabilities on the statement of operations and comprehensive loss.

### ***Redeemable convertible preferred stock tranche obligations***

The obligations to issue additional shares of our Series A-1 redeemable convertible preferred stock in two tranches at a fixed price at future dates were determined to be freestanding instruments within the scope of ASC 480, *Distinguishing Liabilities from Equity*. On issuance, we recorded the redeemable convertible preferred stock tranche asset and liability on the balance sheet at their estimated fair value. The fair value of our redeemable convertible preferred stock tranche asset and liability was calculated using a standard forward pricing model. The estimated probability and timing of achievement of underlying milestone event and the discount rate were significant unobservable inputs used to determine the estimated fair value of the entire instrument. These tranche obligations were remeasured to fair value at each reporting period until settlement, with the net change in fair value recognized as a gain or loss on remeasurement within net change in fair value of redeemable convertible preferred stock tranche obligations in the statements of operations and comprehensive loss.

### ***Stock-based compensation***

We recognize compensation costs related to stock-based awards to employees and non-employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards. The Black-Scholes option pricing model requires the use of subjective assumptions to determine the fair value of stock-based awards including:

- *Fair Value of Common Stock* – Historically, for all periods prior to the IPO in November 2023, fair values of the shares of common stock underlying our share-based awards were estimated on each grant date by our board of directors. Our board of directors considered third-party valuations of our common stock, as well as our board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. After the completion of the IPO, the fair value of each share of underlying common stock is determined based on the closing price of our common stock as reported on the date of grant on the Nasdaq Global Select Market.

- *Expected Term* – The expected term assumption represents the weighted-average period that our share-based awards are expected to be outstanding. We have opted to use the “simplified method” for estimating the expected term of the options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of restricted stock awards was determined using the vesting term of the award.
- *Expected Volatility* – Because we do not have sufficient trading history for our common stock, for all stock options granted to date, the volatility data was estimated based on a study of publicly traded industry peer companies. For purposes of identifying these peer companies, we considered the industry, stage of development, size, and financial leverage of potential comparable companies.
- *Expected Dividend* –The Black-Scholes option pricing model calls for a single expected dividend yield as an input. We currently have no history or expectation of paying cash dividends on our common stock.
- *Risk-Free Interest Rate* – The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the equity-settled award.

We will continue to use judgment in evaluating the assumptions utilized for our stock-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes option pricing model, the amount of stock-based compensation expense we recognize in our financial statements includes stock option forfeitures as they occur. 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 expenses could be materially different.

#### **Emerging growth company and smaller reporting company status**

We are an “emerging growth company”, as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We have elected to 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 the market value of 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 the market value of 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.

#### **Recent accounting pronouncements**

See Note 2 to our financial statements included elsewhere in this Annual Report on Form 10-K for more information.

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

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

**Item 8. Financial Statements and Supplementary Data.**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of CARGO Therapeutics, Inc.

### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of CARGO Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

### **Basis for Opinion**

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

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

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

/s/ Deloitte & Touche LLP

San Francisco, California

March 21, 2024

We have served as the Company's auditor since 2023.

**CARGO Therapeutics, Inc.**  
**Balance Sheets**  
*(in thousands, except share and per share data)*

	December 31,	
	2023	2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 405,732	\$ 1,872
Prepaid expenses and other current assets	3,745	2,055
Total current assets	409,477	3,927
Operating lease right-of-use assets	28,222	2,165
Restricted cash	567	—
Property and equipment, net	10,379	3,368
Other non-current assets	4,391	783
Total assets	<u>\$ 453,036</u>	<u>\$ 10,243</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 5,013	\$ 3,483
Accrued clinical and research and development expenses	7,242	1,646
Accrued expenses and other current liabilities	6,629	3,391
Operating lease liabilities, current	2,278	1,006
Convertible notes—related party	—	11,635
Convertible notes	—	9,619
Derivative liabilities	—	12,705
Financial commitment liabilities—related party	—	412
Financial commitment liabilities	—	240
Total current liabilities	21,162	44,137
Operating lease liabilities, non-current	26,263	1,092
Other non-current liabilities	225	250
Total liabilities	47,650	45,479
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Convertible preferred stock, \$0.001 par value; 11,000,000 shares authorized and 810,700 issued and outstanding at December 31, 2022 (aggregate liquidation preference of \$11,000 at December 31, 2022)	—	1
Common stock, \$0.001 par value; 500,000,000 and 29,000,000 shares authorized at December 31, 2023 and 2022, respectively; 41,205,551 and 1,091,800 shares issued and outstanding at December 31, 2023 and 2022, respectively	41	1
Additional paid-in capital	550,491	11,761
Accumulated deficit	(145,146)	(46,999)
Total stockholders' equity (deficit)	405,386	(35,236)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 453,036</u>	<u>\$ 10,243</u>

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

**CARGO Therapeutics, Inc.**  
**Statements of Operations and Comprehensive Loss**  
*(in thousands, except share and per share data)*

	Year ended December 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 75,791	\$ 29,373
General and administrative	20,919	5,398
Total operating expenses	96,710	34,771
Loss from operations	(96,710)	(34,771)
Interest expense	(1,604)	(4,942)
Net change in fair value of redeemable convertible preferred stock tranche obligations	(8,783)	—
Change in fair value of derivative liabilities	6,453	(1,216)
Loss on extinguishment of convertible notes	(2,316)	—
Other income (expense), net	4,813	(22)
Net loss and comprehensive loss	\$ (98,147)	\$ (40,951)
Net loss per share attributable to common stockholders, basic and diluted	\$ (16.53)	\$ (104.40)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	5,938,782	392,268

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

**CARGO Therapeutics, Inc.**  
**Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**Year Ended December 31, 2023**  
*(in thousands, except share data)*

	Redeemable Convertible		Convertible				Additional Paid-In Capital	Accumulate d Deficit	Total Stockholders' Equity (Deficit)
	Preferred Stock		Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balances at December 31, 2022</b>	—	\$ —	810,700	\$ 1	1,091,800	\$ 1	\$ 11,761	\$ (46,999)	\$ (35,236)
Reclassification of Series Seed redeemable convertible preferred stock	810,700	9,830	(810,700)	(1)	—	—	(9,829)	—	(9,830)
Issuance of Series A-1 redeemable convertible preferred stock, net of issuance costs of \$841 and convertible preferred stock tranche asset and liability of \$7,317 on issuance and including reclassification of preferred stock tranche asset and liability of \$16,100 on settlement	14,796,010	208,701	—	—	—	—	—	—	—
Issuance of Series A-2 redeemable convertible preferred stock upon conversion of convertible notes	3,229,851	35,576	—	—	—	—	—	—	—
Issuance of common stock on initial public offering, net of commissions and offering costs of \$5,579	—	—	—	—	21,262,181	21	291,007	—	291,028
Conversion of redeemable convertible preferred stock to common stock on initial public offering	(18,836,561)	(254,107)	—	—	18,836,561	19	254,088	—	254,107
Issuance of restricted stock awards	—	—	—	—	1,874	—	—	—	—
Vesting of restricted stock awards	—	—	—	—	—	—	103	—	103
Repurchase of restricted stock awards	—	—	—	—	(14,652)	—	—	—	—
Exercise of stock options	—	—	—	—	27,787	—	34	—	34
Stock-based compensation	—	—	—	—	—	—	3,327	—	3,327
Net loss	—	—	—	—	—	—	—	(98,147)	(98,147)
<b>Balances at December 31, 2023</b>	—	\$ —	—	\$ —	41,205,551	\$ 41	\$ 550,491	\$ (145,146)	\$ 405,386

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



**CARGO Therapeutics, Inc.**  
**Statement of Convertible Preferred Stock and Stockholders' Deficit**  
**Year Ended December 31, 2022**  
*(in thousands, except share data)*

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balances at December 31, 2021</b>	405,350	\$ 1	810,699	\$ 1	\$ 5,871	\$ (6,048)	\$ (175)
Issuance of Series Seed convertible preferred stock	405,350	—	—	—	5,500	—	5,500
Issuance of restricted stock awards	—	—	213,496	—	3	—	3
Vesting of restricted stock awards	—	—	—	—	18	—	18
Issuance of common shares for license	—	—	67,605	—	72	—	72
Stock-based compensation expense	—	—	—	—	297	—	297
Net loss	—	—	—	—	—	(40,951)	(40,951)
<b>Balances at December 31, 2022</b>	<u>810,700</u>	<u>\$ 1</u>	<u>1,091,800</u>	<u>\$ 1</u>	<u>\$ 11,761</u>	<u>\$ (46,999)</u>	<u>\$ (35,236)</u>

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

**CARGO Therapeutics, Inc.**  
**Statements of Cash Flows**  
*(in thousands)*

	Year ended December 31,	
	2023	2022
<b>OPERATING ACTIVITIES</b>		
Net loss	\$ (98,147)	\$ (40,951)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net change in fair value of redeemable convertible preferred stock tranche obligations	8,783	—
Stock-based compensation expense	3,327	297
Loss on extinguishment of convertible notes	2,316	—
Amortization of operating lease right-of-use assets	2,201	1,040
Noncash interest expense	1,604	4,942
Depreciation	1,491	404
Acquired in-process research and development	1,505	1,013
Change in fair value of derivative liabilities	(6,453)	1,216
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,590)	(1,912)
Other non-current assets	(3,608)	(267)
Accounts payable	757	2,819
Accrued clinical and research and development expenses	4,673	1,222
Accrued expenses and other current liabilities	3,792	2,175
Operating lease liabilities	(1,815)	(1,070)
Net cash used in operating activities	<u>(81,164)</u>	<u>(29,072)</u>
<b>INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(8,277)	(2,724)
Purchase of in-process research and development	(715)	(558)
Net cash used in investing activities	<u>(8,992)</u>	<u>(3,282)</u>
<b>FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock on initial public offering, net of commissions	296,607	—
Proceeds from issuance of redeemable convertible preferred stock and tranche obligations, net of issuance costs	199,918	—
Proceeds from issuance of convertible notes, net of issuance costs -related party	2,212	15,948
Proceeds from issuance of convertible notes, net of issuance costs	1,286	12,505
Proceeds from issuance of convertible preferred stock and tranche commitment, net of issuance costs	—	5,500
Proceeds from issuance of restricted stock awards	—	232
Proceeds from exercise of stock options	34	—
Payment of deferred initial public offering costs	(5,474)	—
Net cash provided by financing activities	<u>494,583</u>	<u>34,185</u>
Net increase in cash, cash equivalents and restricted cash	404,427	1,831
Cash and cash equivalents at beginning of period	1,872	41
Cash, cash equivalents, and restricted cash at end of period	<u>406,299</u>	<u>1,872</u>
<b>COMPONENTS OF CASH, CASH EQUIVALENTS, AND RESTRICTED CASH</b>		
Cash and cash equivalents	\$ 405,732	\$ 1,872
Restricted cash	567	—
Total cash, cash equivalents, and restricted cash	<u>\$ 406,299</u>	<u>\$ 1,872</u>

**CARGO Therapeutics, Inc.**  
**Statements of Cash Flows**  
*(in thousands)*

	Year ended December 31,	
	2023	2022
<b>SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES</b>		
Reclassification of shares of Series Seed redeemable convertible preferred stock to mezzanine equity	\$ 9,830	\$ —
Conversion of convertible notes to shares of Series A-2 redeemable convertible preferred stock	\$ 35,576	\$ —
Reclassification of tranche obligation asset to Series A-1 redeemable convertible preferred stock	\$ 1,910	\$ —
Reclassification of tranche obligation liability to Series A-1 redeemable convertible preferred stock	\$ 18,010	\$ —
Conversion of redeemable convertible preferred stock into common stock on completion of initial public offering	\$ 254,107	\$ —
Purchase of property and equipment in accounts payable and accrued expenses and other current liabilities	\$ 883	\$ 623
In-process research and development costs in accounts payable, accrued expenses and other current liabilities, and other non-current liabilities	\$ 1,273	\$ 383
Issuance of shares in exchange for in-process research and development	\$ —	\$ 72
Deferred offering costs related to initial public offering included in accounts payable and accrued expenses and other current liabilities	\$ 105	\$ —
Deferred issuance costs for second tranche of Series A-1 redeemable convertible preferred stock in accounts payable and accrued expenses and other current liabilities	\$ —	\$ 74

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

**CARGO Therapeutics, Inc.**  
**Notes to Financial Statements**

**1. Organization**

***Description of the business***

CARGO Therapeutics, Inc. (the “Company”) was incorporated in the state of Delaware in December 2019 as Syncopation Life Sciences, Inc. and changed its name to CARGO Therapeutics, Inc. in September 2022. It is a clinical-stage biotechnology company positioned to advance next generation, potentially curative cell therapies for cancer patients. The Company’s programs, platform technologies, and manufacturing strategy are designed to directly address the key limitations of approved cell therapies, including limited durability of effect, suboptimal safety and unreliable supply. The Company’s lead program, CRG-022, an autologous CD22 chimeric antigen receptor (“CAR”) T-cell therapy, has demonstrated robust safety, activity and manufacturability in clinical trials and is currently being studied in a potentially pivotal Phase 2 clinical trial for the treatment of large B-cell lymphoma (“LBCL”). The Company is also leveraging its proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multi-functional genetic “cargo” designed to enhance CAR T-cell persistence, as well as help safeguard against tumor resistance and T-cell exhaustion.

Since its founding, the Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, raising capital, establishing licensing arrangements, building its proprietary platform technologies, discovering its product candidates, establishing its intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of its product candidates and related raw materials, and providing general and administrative support for these operations.

***Reverse Stock Split***

On November 1, 2023, the Company’s board of directors approved an amended and restated certificate of incorporation to effect a reverse split of shares of the Company’s common stock and redeemable convertible preferred stock on a 13.5685-for-1 basis (the “Reverse Stock Split”) which was effected on November 3, 2023. The par value and authorized number of shares of common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All share data and per share data amounts for all periods presented in the audited financial statements and notes thereto have been retrospectively adjusted to reflect the effect of the Reverse Stock Split.

***Initial Public Offering***

On November 14, 2023, the Company closed its initial public offering (“IPO”), pursuant to which it issued and sold an aggregate of 18,750,000 shares of its common stock at a public offering price of \$15.00 per share and on November 21, 2023, the Company issued and sold 2,512,181 additional shares of its common stock to the underwriters of the IPO pursuant to the partial exercise of their option to purchase additional shares, resulting in net proceeds of \$291.0 million, after deducting underwriting discounts, commissions and other offering expenses. Upon the closing of the IPO, the Company’s 18,836,561 outstanding shares of redeemable convertible preferred stock then outstanding automatically converted into 18,836,561 shares of common stock (see Note 7). Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding.

In connection with the closing of its IPO, on November 14, 2023, the Company’s certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value \$0.001 per share and 50,000,000 shares of preferred stock, par value of \$0.001 per share.

***Liquidity***

Since inception, the Company has incurred significant operating losses and negative cash flows, and it expects that it will continue to incur losses and negative cash flows for the foreseeable future as it continues its research and development efforts, advances its product candidates through preclinical and clinical development, enhances its platforms and programs, expands its product pipeline, seeks regulatory approval, prepares for commercialization, hires

additional personnel, protects its intellectual property and grows its business. As of and for the year ended December 31, 2023, the Company had an accumulated deficit of \$145.1 million, cash and cash equivalents of \$405.7 million and negative cash flows from operations of \$81.2 million. The Company believes its existing cash and cash equivalents will be sufficient to support operations for at least 12 months from the issuance of these financial statements.

## **2. Summary of significant accounting policies**

### ***Basis of presentation***

The Company has prepared the accompanying financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”). The financial statements are presented in U.S. dollars.

### ***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, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Actual results could differ from those estimates and such differences could be material to the financial position and results of operations.

Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses, the fair value of derivative liabilities and the initial fair value of the financial commitment liabilities related to the convertible notes, valuation of the redeemable convertible preferred stock tranche asset and liability, valuation of deferred tax assets, the fair value of equity instruments, equity-based instruments, stock-based compensation, and the determination of the incremental borrowing rate used to measure right-of-use assets and lease liabilities for the Company’s operating leases.

### ***Risks and uncertainties***

The Company is subject to all of the risks inherent in an early-stage company advancing new biotechnologies. These risks include, but are not limited to, the need for substantial additional financing, limited management resources, dependence upon medical acceptance of the product in development, regulatory approvals, successful clinical trials, availability, and willingness of patients to participate in human trials, and competition in the biopharmaceutical industry. The Company’s operating results may be materially affected by the preceding factors.

### ***Segments***

Operating segments are defined as components of an entity for which separate financial information is available and regularly reviewed by the chief operating decision maker, its Chief Executive Officer, in deciding how to allocate resources to an individual segment and in assessing performance. The Company has determined that it operates as one operating and reporting segment.

### ***Cash, cash equivalents, and restricted cash***

The Company considers all highly liquid investments purchased with an original maturity of three months or less on the date of purchase to be cash equivalents. Cash equivalents primarily consist of money market funds that are stated at fair value.

The Company considers restricted cash as cash and cash equivalents that cannot be withdrawn or used for general operating activities. Restricted cash consists of a letter of credit with a financial institution related to one of the Company’s leases.

### ***Issuance costs related to equity***

The Company allocates issuance costs between the individual freestanding instruments identified on a relative fair value basis. Issuance costs associated with the issuance of stock or equity contracts (i.e., redeemable convertible preferred stock) are recorded as a charge against the gross proceeds of the offering.

The Company capitalizes certain legal, accounting, and other third-party fees that are directly related to the Company's equity offering until such offering is consummated. On November 14, 2023, upon completion of IPO the Company recognized offering costs of \$5.6 million as a reduction from gross proceeds associated with the IPO through additional paid-in capital in the accompanying balance sheet.

### ***Property and equipment, net***

Property and equipment, net is stated at cost, subject to adjustments for impairment, less accumulated depreciation. Depreciation is calculated using the straight-line method over the useful lives of the assets as follows:

Laboratory equipment	3 to 5 years
Furniture and fixtures	3 to 5 years
Computer equipment	3 to 5 years
Leasehold improvements	Shorter of useful life or remaining lease term

Maintenance and repairs are charged to expense as incurred, and improvements are capitalized and depreciated over their useful life as indicated above. Upon retirement or sale of the assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gains or losses are recorded in the statement of operations and comprehensive loss.

### ***Impairment of long-lived assets***

The Company reviews long lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount to the future net undiscounted cash flows the assets are expected to generate. If such assets are considered to be impaired, the impairment charge is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There have been no such impairments of long-lived assets during the periods presented.

### ***Asset Acquisitions***

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development, ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date.

### ***Financial commitment liabilities***

The Company's convertible note purchase agreements executed in April 2022 and October 2022 ("2022 Convertible Notes") included financial commitments to issue additional convertible notes to the noteholders in tranches (see Note 6) that were determined to be freestanding instruments that should be classified as liabilities. The freestanding instruments met the scope exception from derivative accounting. The proceeds of the first tranche of each of the 2022 Convertible Notes were allocated to the convertible notes and financial commitment liabilities based on their relative fair value at the date of issuance and not subsequently remeasured. The proceeds allocated to the financial commitment liabilities create a discount on the respective convertible note that is amortized as interest expense in the statements of operations and comprehensive loss using the effective interest rate method over the term of the respective convertible note. Upon settlement of each tranche, the respective portion of the financial commitment liabilities is reclassified to the carrying amount of the respective convertible note.

### ***Income taxes***

The Company accounts for income taxes using the asset and liability method whereby deferred tax asset and liability accounts are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are currently in effect. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Financial statement effects of uncertain tax positions are recognized when it is more likely than not, based on the technical merits of the position, that it will be sustained upon examination. Interest and penalties related to unrecognized tax benefits are included within the provision (benefit) for income tax. To date, there have been no interest or penalties charged in relation to the unrecognized tax benefits.

### ***Derivative liabilities***

The 2022 Convertible Notes contain certain embedded redemption features that are not clearly and closely related to the debt host instruments (see Note 6). These features are bifurcated from the host instruments and recorded at fair value on the date of issuance as derivative liabilities in accordance with Accounting Standards Codification (“ASC”) 815-15, *Derivatives and Hedging—Embedded Derivatives*. The derivative liabilities are remeasured to fair value each reporting period until settlement or extinguishment, with changes in the fair value recorded as a change in fair value of derivative liabilities in the statements of operations and comprehensive loss. Derivative liabilities are classified in the balance sheets as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

### ***Redeemable convertible preferred stock tranche obligations***

The obligations to issue additional shares of the Company’s Series A-1 redeemable convertible preferred stock in two tranches at a fixed price at future dates were determined to be freestanding financial instruments within the scope of ASC 480, *Distinguishing Liabilities from Equity* (“ASC 480”). On issuance, the Company recorded the redeemable convertible preferred stock tranche asset and liability on the balance sheet at their respective fair values. These tranche obligations are subject to remeasurement at each balance sheet date, with the net change in fair value recognized as a gain or loss on remeasurement within net change in fair value of redeemable convertible preferred stock tranche obligations in the statements of operations and comprehensive loss until settlement.

### ***Leases***

The Company is a lessee in a non-cancellable operating lease for laboratory and office facilities. The Company determines if an arrangement is or contains a lease at inception, which is the date on which the terms of the contract are agreed to, and the agreement creates enforceable rights and obligations. A contract is or contains a lease when (i) explicitly or implicitly identified assets have been deployed in the contract and (ii) the customer obtains substantially all of the economic benefits from the use of that underlying asset and has the right to control how and for what purpose the asset is used during the term of the contract. The Company also considers whether its service arrangements include the right to control the use of an asset.

For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use (“ROU”) asset and lease liability at the lease commencement date and thereafter if modified. Operating lease ROU assets represent the Company’s right to use an underlying asset for the lease term and operating lease liabilities represent the Company’s obligation to make the contractual lease payments over the lease term. The operating lease ROU asset is initially measured at cost, which comprises the initial amount of the operating lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received. The operating lease liability is initially measured at the present value of the unpaid lease payments at the lease commencement date. The operating lease liability is subsequently measured at amortized cost using the effective-interest method. The lease term includes any renewal options that the Company is reasonably assured to exercise. As the rate implicit on the Company’s leases is not readily determinable, the Company uses its secured incremental borrowing rate to determine the present value of lease payments. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term and in a similar economic environment. The Company has elected not to record leases with an original term of 12 months or less on its balance sheets and recognizes those lease

payments in operating expenses in the statements of operations and comprehensive loss. During the years ended December 31, 2023 and 2022, there were no material short-term leases.

In addition, the Company's leases may require payment of additional costs, such as utilities, maintenance, and other operating costs, which are generally referred to as non-lease components and vary based on future outcomes. The Company has elected not to separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of an operating ROU asset and lease liability. Any variable expenses are recognized in operating expenses as incurred. Rent expense for an operating lease liability is recognized on a straight-line basis over the lease term and is included in operating expenses in the statements of operations and comprehensive loss.

#### ***Research and development expenses and accruals***

Research and development expenses consist of direct costs, including manufacturing and technical operations, preclinical and clinical fees paid to clinical research organizations, supplies, health authority filings, technology licenses and in-process research and development (IPR&D) assets as well as indirect costs consisting of employee-related costs and allocated facilities and other operating costs. Research and development costs are expensed as incurred. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses until the related goods are delivered or services are performed. Such payments are evaluated for current or long-term classification based on when such services are expected to be received.

The Company estimates manufacturing and technical operations, preclinical study and clinical trial and research and development expenses based on the services performed, pursuant to contracts with research institutions and third-party service providers that conduct and manage preclinical studies and clinical trials and research services on its behalf. The Company records the costs of research and development activities based on the estimated services provided but not yet invoiced and includes these costs in accrued expenses and other current liabilities in the balance sheets. These costs are a component of the Company's research and development expenses.

The Company accrues these costs based on factors such as estimates of the work completed in accordance with agreements established with its third-party service providers. The Company makes judgments and estimates in determining the accrued expenses balance. As actual costs become known, the Company adjusts its accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from the Company's estimates, resulting in adjustments to expenses in future periods. Changes in these estimates that result in material changes to the Company's accrued expenses could materially affect the Company's results of operations. Contingent milestone payments, if any, are expensed when the milestone results are probable and estimable, which is generally upon the achievement of the milestone.

#### ***Stock-based compensation***

The Company provides share-based payments in the form of stock options and restricted stock awards. For awards only subject to service conditions, the Company uses the straight-line attribution method for recognizing compensation expense over the requisite service period, which is generally the vesting period of the award. Compensation expense is recognized on awards ultimately expected to vest. Forfeitures are recorded when they occur.

For awards with performance vesting conditions, the Company evaluates the probability of achieving the performance condition at each reporting date. No compensation expense is recognized for awards subject to performance conditions until it is probable that the performance condition will be met. If the performance condition is probable of being achieved, the Company recognizes expense for such performance awards over the requisite service period using the accelerated attribution method.

The Company estimates the fair value of stock option awards and restricted stock awards on the grant date using a Black-Scholes option pricing model. The Company estimates the expected option lives using the simplified method, volatility using stock prices of peer companies, risk-free rates using the implied yield currently available on U.S.



Treasury zero-coupon issues with a remaining term equal to the expected term, and dividend yield based on the Company's history of paying no dividends and expectation of paying no cash dividends on its common stock.

#### ***Net loss per share attributable to common stockholders***

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed using the weighted-average number of shares of common stock outstanding during the period excluding unvested restricted stock subject to repurchase. Diluted net loss per share attributable to common stockholders is computed using the sum of the weighted-average number of shares of common stock outstanding during the period and the effect of dilutive securities.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company.

Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. As the Company was in a net loss position for the years ended December 31, 2023 and 2022, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders because the effects of potentially dilutive securities are antidilutive.

#### ***Comprehensive loss***

Comprehensive loss represents the change in the Company's stockholders' deficit from all sources other than investments by or distributions to stockholders. The Company has no items of other comprehensive loss; as such, net loss equals comprehensive loss.

#### ***Emerging growth company status***

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

#### ***Recently adopted accounting pronouncements***

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which replaces the existing incurred loss impairment model with an expected credit loss model and requires a financial asset measured at amortized cost to be presented at the net amount expected to be collected. The Company adopted ASU 2016-13 on January 1, 2023, using a modified retrospective approach. The adoption did not have a material impact on the Company's financial statements.

**Recently issued accounting pronouncements not yet adopted**

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting—Improvements to Reportable Segment Disclosures*. ASU 2023-07 requires disclosure of incremental segment information on an interim and annual basis and provides new segment disclosure requirements for entities with a single reportable segment. ASU 2023-07 is effective for all public companies for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The Company is assessing the impact of the adoption of this standard on its financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes—Improvements to Income Tax Disclosures* (“ASU 2023-09”). ASU 2023-09 requires consistent categories and greater disaggregation of information in the rate reconciliation, income taxes paid disaggregated by jurisdiction and certain other amendments to improve the effectiveness of income tax disclosures. ASU 2023-09 is effective for the Company beginning on January 1, 2025, with early adoption permitted. The Company is assessing the impact of the adoption of this standard on its financial statements.

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the accompanying financial statements and disclosures.

**3. Fair value measurement**

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Carrying amounts of certain of the Company’s financial instruments including, cash, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate fair value due to the short-term nature of these instruments.

On a recurring basis, the Company measures certain financial liabilities at fair value. There were no transfers between levels during the years ended December 31, 2023 and 2022. The following tables summarize the Company’s financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
<b>Assets:</b>				
Money market funds	\$ 398,017	\$ —	\$ —	\$ 398,017
<b>Total financial assets</b>	<b>\$ 398,017</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 398,017</b>
	December 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
<b>Liabilities:</b>				
Derivative liabilities	\$ —	\$ —	\$ 12,705	\$ 12,705
<b>Total financial liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 12,705</b>	<b>\$ 12,705</b>

**Derivative liabilities**

In April and October 2022, the Company executed convertible note purchase agreements with its existing investors (see Note 7). The 2022 Convertible Notes contained certain embedded features requiring bifurcation as a single compound derivative instrument for each tranche funded. The derivative liabilities were measured at fair value using Level 3 inputs. The fair value of the derivative liabilities was estimated using a “with-and-without” method. The “with-and-without” methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the embedded derivative. The difference between the entire instrument with the embedded derivatives and the instrument without the embedded derivatives is the fair value of the derivative liabilities. The estimated probability and timing of underlying events triggering the exercisability of the put option and conversion features contained within the 2022 Convertible Notes, forecasted cash flows and the discount rate were significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative. Significant increases (decreases) in any of those inputs in isolation would result in a significantly lower (higher) fair value measurement. The derivative liabilities are remeasured at each reporting period and the changes are recognized as a change in fair value of derivative liabilities on the statement of operations and comprehensive loss. The derivative liabilities were settled in February 2023 upon conversion of the 2022 Convertible Notes into Series A-2 redeemable convertible preferred stock (see Note 6).

The following table summarizes the significant inputs used in the valuation of the derivative liabilities:

	On Issuance Date of January 18, 2023	February 9, 2023
Expected term to achievement underlying triggering event (in years)	0.1 – 0.2	—
Probability of achievement of triggering event	0.0% – 95.0%	100.0%
Discount rate	75.0%	75.0%

The following table provide a summary of the change in the estimated fair value of the Company’s derivative liabilities during the year ended December 31, 2023:

	Derivative Liabilities (in thousands)
Balance as of December 31, 2022	\$ 12,705
Additions <sup>(1)</sup>	2,133
Change in fair value	(6,453)
Settlement	(8,385)
Balance as of December 31, 2023	\$ —

<sup>(1)</sup> The additions to derivative liabilities in the year ended December 31, 2023 relate to the embedded derivative bifurcated from the final tranche of the 2022 Convertible Notes that was issued in January 2023.

**Financial commitment liabilities**

The 2022 Convertible Notes included financial commitments to issue additional convertible notes to the noteholders in tranches (see Note 6). The proceeds of the issuance of the first tranche of each of the convertible notes issued in April 2022 and October 2022 were allocated to the convertible notes and financial commitment liabilities based on their relative fair value of \$0.7 million and \$1.2 million, respectively, of which \$0.4 million and \$0.7 million were associated with a related party, respectively, at the date of issuance and not subsequently remeasured. The fair value of the financial commitment liabilities on issuance was measured using the “with-and-without” method based on Level 3 inputs. The estimated probability and timing of underlying events triggering the closing of the subsequent tranches, forecasted cash flows and the discount rate were significant unobservable inputs used to determine the estimated fair value of the entire instrument.

The following table summarizes the significant inputs used in the valuation of the financial commitment liabilities on issuance:

	April 2022 Convertible Notes	October 2022 Convertible Notes
Expected term to achievement of milestone (in years)	0.3 – 0.5	0.1 – 0.3
Probability of achievement of milestone	81.0% – 90.0%	90.3% – 95.0%
Discount rate	1.2% – 1.9%	3.9% – 4.4%

***Series Seed tranche commitment***

The Series Seed stock purchase agreement included an obligation to issue additional shares of Series Seed convertible preferred stock in a future closing (see Note 7). The Series Seed tranche commitment was recorded at relative fair value upon the issuance of shares in the first closing and was not subsequently remeasured. The Series Seed tranche commitment is considered a contingent forward and the standard forward pricing model was used to measure the fair value on issuance using Level 3 inputs as follows:

	Series Seed Tranche Commitment
Expected term to achievement of milestone (in years)	0.9
Probability of achievement of milestone	90.0%
Discount rate	0.1%

***Redeemable convertible preferred stock tranche obligations***

The fair value of the Company’s redeemable convertible preferred stock tranche asset and liability (see Note 7) was calculated using an option pricing model using Level 3 inputs not observable in the market. Significant increases (decreases) in any of those inputs in isolation would result in a significantly lower (higher) fair value measurement. On settlement, the fair value of the redeemable convertible preferred stock tranche liability was calculated based on two scenarios, stay-private and IPO with early and late exit dates, each of which were probability weighted. The stay private scenario, weighted at a 30% probability, estimated the fair value using an option pricing model. The IPO scenario, weighted at a 70% probability, estimated the value of the Company upon an IPO at \$380.0 million with an early IPO exit in less than 0.1 years and a late IPO exit in 0.3 years.

The redeemable convertible preferred stock tranche obligations are considered a contingent forward and the standard forward pricing model was used for the option pricing model with the following key assumptions:

	Redeemable Convertible Preferred Stock Tranche Asset		Redeemable Convertible Preferred Stock Tranche Liability	
	On Issuance Date February 9, 2023	On Settlement Date of July 7, 2023	On Issuance Date February 9, 2023	On Settlement Date of October 27, 2023
Expected term to achievement of milestone (in years)	0.4	—	0.8	—
Probability of achievement of milestone	90.0%	100%	63.0%	99.0%
Discount rate	4.9%	—	4.9%	5.6%

The following table summarizes the changes in the fair value of the redeemable convertible preferred stock tranche asset and liability:

	Redeemable Convertible Preferred Stock Tranche Asset	Redeemable Convertible Preferred Stock Tranche Liability
	(in thousands)	
Balance as of December 31, 2022	\$ —	\$ —
Initial recognition	1,788	(9,105)
Change in fair value	122	(8,905)
Settlement	(1,910)	18,010
Balance as of December 31, 2023	\$ —	\$ —

#### 4. Balance sheet components

##### *Prepaid expenses and other current assets*

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2023	2022
	(in thousands)	
Prepaid research and development	\$ 825	\$ 1,428
Other receivables	1,739	476
Prepaid other	1,181	151
Total prepaid expenses and other current assets	\$ 3,745	\$ 2,055

##### *Property and equipment, net*

Property and equipment, net consisted of the following:

	December 31,	
	2023	2022
	(in thousands)	
Laboratory equipment	\$ 9,644	\$ 2,712
Furniture and fixtures	87	34
Computer equipment	593	47
Leasehold improvements	134	105
Construction in progress	1,833	891
Property and equipment at cost	12,291	3,789
Less: accumulated depreciation	(1,912)	(421)
Property and equipment, net	\$ 10,379	\$ 3,368

Depreciation expense for the years ended December 31, 2023 and 2022 was \$1.5 million and \$0.4 million, respectively.

**Accrued expenses and other current liabilities**

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2023	2022
	(in thousands)	
Accrued compensation and related expenses	\$ 5,391	\$ 2,385
Accrued purchases of property and equipment	112	623
Accrued deferred offering costs related to the initial public offering	95	—
Other	1,031	383
<b>Total accrued expenses and other current liabilities</b>	<b>\$ 6,629</b>	<b>\$ 3,391</b>

**5. Leases**

In December 2023, the Company entered into a 7-year lease for 99,557 square feet of lab and office space in San Carlos, California. The agreement provides for two options to renew for three years which the Company is not reasonably certain to exercise. The Company is required to maintain a letter of credit for \$0.6 million which has been classified as non-current restricted cash on the balance sheet.

The Company also leases 31,117 square feet of lab and office space in San Mateo, California which expires in November 2024. The Company was a sublessor in two agreements for a combined 2,300 square feet of the Company's leased premises which expired in May 2023 and October 2023.

The future payments associated with the Company's operating lease liabilities as of December 31, 2023 are as follows:

	Amount	
	(in thousands)	
2024	\$	2,988
2025		4,676
2026		7,224
2027		7,441
Thereafter		25,784
Total undiscounted lease payments		48,113
Less: imputed interest		(19,572)
<b>Total operating lease liabilities</b>	<b>\$</b>	<b>28,541</b>

A summary of total lease costs and other information for the periods relating to the Company's operating leases was as follows:

	Year ended December 31,	
	2023	2022
	(in thousands)	
Operating lease cost	\$ 2,873	\$ 1,282
Variable lease cost	620	317
Sublease income	(290)	(240)
<b>Total lease cost</b>	<b>\$ 3,203</b>	<b>\$ 1,359</b>

	December 31,	
	2023	2022
<b>Other information:</b>		
Weighted-average remaining lease term (in years)	6.7	1.9
Weighted-average discount rate	13.6%	9.6%

Supplemental cash flow and noncash information related to the Company’s operating leases were as follows:

	Year ended December 31,	
	2023	2022
(in thousands)		
<b>Cash flows from operating activities:</b>		
Cash paid for amounts included in the measurement of lease liabilities	\$ 2,495	\$ 1,312
<b>Right-of-use assets obtained in exchange for lease obligations:</b>		
Total right-of-use assets capitalized	\$ 28,258	\$ —

## 6. Convertible Notes

In April 2022, the Company executed a convertible note purchase agreement with its existing investors for total proceeds of up to \$25.0 million (the “April 2022 Convertible Notes”). The investors committed to purchase the notes in three tranches upon achievement of certain milestones, which were funded in April, August and October 2022 for aggregate gross proceeds of \$20.0 million, of which \$10.6 million was from a related party (see Note 11). The Company incurred \$0.1 million in issuance costs for the April 2022 Convertible Notes. All three tranches had a maturity date of April 26, 2023. The Company had the option to request a fourth tranche of up to \$5.0 million at the discretion of the investors under certain specific criteria. In February 2023, the April 2022 Convertible Notes were settled in connection with the Series A redeemable convertible preferred stock financing (see Note 7) and the option to request the fourth tranche expired.

In October 2022, the Company executed a convertible note purchase agreement with the same terms and with the same investors in the April 2022 Convertible Notes for total proceeds of up to \$12.0 million (the “October 2022 Convertible Notes”), of which \$5.4 million was from a related party. The investors committed to purchase the notes in three tranches upon achievement of certain milestones, of which the first two tranches were issued in October and December 2022 for aggregate gross proceeds of \$8.5 million. The Company incurred \$16,000 in issuance costs for the funded October 2022 Convertible Notes. In January 2023, the third tranche was issued upon achieving the third milestone for gross proceeds of \$3.5 million, including \$2.2 million issued to a related party. All three tranches had a maturity date of October 28, 2023. In February 2023, the October 2022 Convertible Notes were settled in connection with the Series A redeemable convertible preferred stock financing (see Note 7).

The 2022 Convertible Notes bear simple interest at 6.0% per annum. The principal and accrued interest could only be repaid prior to maturity upon consent of a majority of the investors or immediately upon demand.

The 2022 Convertible Notes were subject to automatic conversion upon the next financing whereby the Company issues its preferred equity securities and raises aggregate gross proceeds of at least \$50.0 million (a “Qualified Financing”). On automatic conversion, the outstanding principal and accrued interest automatically convert into the convertible preferred stock issued in the Qualified Financing at 75% of the lowest cash price per share. The 2022 Convertible Notes were also subject to settlement by way of voluntary conversion that is not a Qualified Financing (a “Non-Qualified Financing”) where a majority of the active investors (investors who have fulfilled their funding commitments) could elect to convert the outstanding principal and interest into convertible preferred stock issued at 75% of the lowest cash price per share. In the event of a “Strategic Transaction” such as upon a change in control whereby another entity acquires the Company or the Company disposes of substantially all its assets upon sale, lease, liquidation, dissolution or winding up, whether voluntary or involuntary, or an IPO, then each active investor could choose to convert the note into the Company’s common stock at a conversion price of \$20.36 per share or redeem the note in cash for 200% of the outstanding balance and 100% of accrued and unpaid interest. For investors who had not fulfilled their funding commitments related to the second and third tranches where the respective milestone conditions have been met, upon a Qualified Financing, a Non-Qualified Financing or a Strategic Transaction, the outstanding principal and interest of the note would automatically convert into shares of common stock at 10% of the then current common stock price.

The Company determined that the financial commitments to issue future tranches were freestanding instruments that did not meet the definition of a derivative and should be classified as liabilities. Upon issuance of the first tranche of the April 2022 Convertible Notes and October 2022 Convertible Notes, the Company recognized \$0.7 million and \$1.2 million, respectively, for the relative fair value of the financial commitment liabilities, of which \$0.4 million and \$0.7 million, respectively, were associated with a related party (see Note 3). Upon settlement of the financial commitments, for the years ended December 31, 2023 and 2022, \$0.7 million and \$1.2 million in financial commitment liabilities, respectively, were reclassified to the carrying amount of the respective convertible notes.

Due to the conversion and redemption features embedded within the 2022 Convertible Notes, the Company bifurcated compound derivative liabilities related to all tranches issued through December 31, 2023 (see Note 3). The aggregate fair value at issuance of the derivative liabilities was \$13.6 million and was subsequently remeasured each reporting period. The allocation of proceeds of the 2022 Convertible Notes to the financial commitment liabilities and embedded derivatives created a discount on the respective convertible note that was amortized using the effective interest rate method over the term of the respective note. For the years ended December 31, 2023 and 2022, the Company recognized \$1.6 million and \$4.9 million, respectively, of non-cash interest expense, including accrued interest, amortization of the debt discount and amortization of debt issuance costs, in the statement of operations and comprehensive loss.

In February 2023, concurrent with the Series A redeemable convertible preferred stock financing (see Note 7), the terms of the 2022 Convertible Notes were amended to specify that the notes would convert into Series A-2 redeemable convertible preferred stock. The other contractual terms including the settlement method and the conversion price of \$10.18 per share remained unchanged. Pursuant to the share settled redemption features as per the original contractual terms of the 2022 Convertible Notes, the Company issued 3,229,851 shares thereby settling \$32.9 million in outstanding principal and accrued interest. Upon settlement, the carrying values of the 2022 Convertible Notes of \$24.9 million and the derivative liabilities of \$8.4 million were derecognized and the Series A-2 redeemable convertible preferred stock was recorded at its fair value of \$35.6 million. The Company recognized a loss on extinguishment of \$2.3 million in the statement of operations and comprehensive loss for the year ended December 31, 2023.

## **7. Preferred Stock**

### **Convertible preferred stock**

#### ***Series Seed stock purchase agreement***

In February 2021, the Company entered into a Series Seed stock purchase agreement for issuance of up to 810,700 shares of the Company's Series Seed convertible preferred stock at a purchase price of \$13.57 per share (the "Original Issuance Price") in two closings. Concurrent with the execution of the agreement, the Company completed its first closing. In the first closing, the Company issued 405,350 shares of its Series Seed convertible preferred stock for aggregate gross proceeds of \$5.5 million, less issuance costs of \$0.1 million.

On issuance, the Company determined that its obligation to issue 405,350 shares of Series Seed convertible preferred stock in a future closing was a freestanding instrument that met the requirements of equity classification in accordance with ASC 815-40, *Derivatives and Hedging — Contracts in Entity's Own Equity*, as it was indexed to the Company's shares and could only be settled in shares. The proceeds of the issuance of the Series Seed convertible preferred stock and issuance costs were allocated to the Series Seed convertible preferred stock and the Series Seed tranche commitment based on their relative fair value. The Company recognized \$0.1 million of the proceeds of the Series Seed convertible preferred stock in equity for the relative fair value of the Series Seed tranche commitment on issuance, with the remaining proceeds allocated to the Series Seed convertible preferred stock. No subsequent remeasurement of the freestanding instrument was required (see Note 3).

In January 2022, the Company completed the second closing and received aggregate net proceeds of \$5.5 million for the issuance of 405,350 shares of Series Seed convertible preferred stock at a purchase price of \$13.57 per share. Upon the second closing, the \$0.1 million related to the Series Seed tranche commitment was reclassified to the carrying value of the Series Seed convertible preferred stock.



**Series A preferred stock purchase agreement**

In February 2023, the Company’s existing and new investors executed the Series A Preferred Stock Purchase Agreement (the “Series A Agreement”) pursuant to which the Company was obligated to sell shares of its redeemable convertible preferred stock immediately at execution and through a second and third tranche. In February 2023, the Company received net proceeds of \$68.1 million from the issue and sale of 5,072,919 shares of Series A-1 redeemable convertible preferred stock and issued 3,229,851 shares of Series A-2 redeemable convertible preferred stock upon conversion of the 2022 Convertible Notes (see Note 6).

Pursuant to the Series A Agreement, through the second tranche, the Company was obligated to sell 3,381,941 shares of its Series A-1 redeemable convertible preferred stock for \$13.57 per share (“Series A-1 Tranche 2”) upon the satisfaction of certain developmental milestones by the end of the third quarter of 2023. Additionally, the Company was obligated to sell 6,341,150 shares of its Series A-1 redeemable convertible preferred stock for \$13.57 per share (“Series A-1 Tranche 3”) upon the satisfaction of certain developmental milestones by the middle of the first quarter of 2024. In July 2023, the Company achieved the milestone under the Series A-1 Tranche 2 and issued and sold 3,381,941 shares of its Series A-1 redeemable convertible preferred stock for net proceeds of \$45.8 million. In October 2023, the Company issued and sold 6,341,150 shares of its Series A-1 redeemable convertible preferred stock as a part of the Series A-1 Tranche 3 closing for proceeds of \$86.0 million.

On issuance, the Company determined that its obligation to issue additional shares of its Series A-1 redeemable convertible preferred stock in future closings were freestanding instruments in accordance with ASC 480. The Series A-1 Tranche 2 obligation was determined to be an asset as the issuance price was deemed to be in excess of the estimated fair value of the stock on the expected milestone achievement date. Conversely, the Series A-1 Tranche 3 obligation was determined to be a liability as the estimated fair value of the stock on the expected milestone achievement date was deemed to be in excess of the issuance price. Accordingly, the Company recognized \$1.8 million and \$9.1 million for the fair value of the redeemable convertible preferred stock tranche asset and liability, respectively, on the balance sheet and the remaining proceeds were allocated to the first tranche of Series A-1 redeemable convertible preferred stock. Changes in fair value of redeemable convertible preferred stock tranche asset and liability in subsequent reporting periods are recognized as a component of change in fair value of preferred stock tranche obligations in the statement of operations and comprehensive loss. In connection with the closing of Series A-1 Tranche 2 in July 2023, the fair value of the redeemable convertible preferred stock tranche asset of \$1.9 million was reclassified to carrying amount of Series A-1 redeemable convertible preferred stock. In connection with the closing of Series A-1 Tranche 3 in October 2023, the fair value of the redeemable convertible preferred stock tranche liability of \$18.0 million was reclassified to carrying amount of Series A-1 redeemable convertible preferred stock.

On November 14, 2023, the Company closed its IPO, and 18,836,561 outstanding shares of redeemable convertible preferred stock then outstanding automatically converted into shares of common stock on a 1:1 basis. Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding.

As of December 31, 2022, convertible preferred stock consisted of the following:

	December 31, 2022				
	Shares Authorized	Shares Issued and Outstanding	Original Issuance Price	Liquidation Preference	Carrying Value
	(in thousands, except share and per share amounts)				
Series Seed	11,000,000	810,700	\$ 13.57	\$ 11,000	\$ 10,855
Total	11,000,000	810,700		\$ 11,000	\$ 10,855

**Classification**

A liquidation or winding up of the Company, including a merger or consolidation in which the Company or a subsidiary of the Company is a constituent party and the Company issues its shares as a part of such merger or consolidation, or the sale of substantially all of the assets, sales or exclusive license of all or substantially all of the intellectual property of the Company, or any other transaction or series of transactions in which more than 50% of the voting power of the Company is disposed of would constitute a redemption event. As of December 31, 2022, these

redemption events were deemed to be within the control of the Company; therefore, in accordance with ASC 480, all shares of Series Seed convertible preferred stock were presented within permanent equity.

Upon closing of the first tranche of shares of Series A-1 redeemable preferred stock and conversion of the 2022 Convertible Notes to shares of Series A-2 redeemable preferred stock on February 9, 2023, the convertible preferred stockholders collectively had the ability to elect a majority of the directors on the Company's board of directors such that a redemption event pursuant to the various rights of shares of the convertible preferred stock was no longer within the control of the Company. In accordance with ASC 480, all shares of Series Seed convertible preferred stock were reclassified from permanent equity to mezzanine equity at fair value, and, on issuance, all shares of Series A-1 and A-2 redeemable convertible preferred stock were classified as mezzanine equity.

## Preferred stock

In connection with the closing of its IPO, the Company's certificate of incorporation was amended and restated to authorize 50,000,000 shares of preferred stock, par value of \$0.001 per share. As of December 31, 2023, no shares of preferred stock were outstanding.

## 8. Common Stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors. The voting, dividend, liquidation, and other rights and powers of the common stock are subject to and qualified by the rights, powers and preferences of preferred stock.

In February 2023, the Company amended and restated its certificate of incorporation to increase the authorized shares of common stock to 320,000,000.

In November 2023, in connection with the closing of its IPO, the Company's certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value \$0.001 per share and a new class of preferred stock (see Note 7). Additionally, all classes of redeemable convertible preferred stock were cancelled.

Common stock issued and outstanding on the balance sheets and statements of stockholders' equity (deficit) includes shares related to restricted stock that are subject to repurchase and therefore are excluded from the reserved common stock in the table below.

The Company's reserved common stock on an as-converted basis for issuance was as follows:

	December 31,	
	2023	2022
Convertible preferred stock	—	810,700
Common stock options issued and outstanding under the Plans	3,720,455	167,882
Remaining shares available for issuance under the Plan	3,893,858	22,928
Remaining shares available for issuance under the ESPP	386,725	—
Total reserved common stock	8,001,038	1,001,510

## 9. Stock-based compensation

### 2021 stock option and grant plan

In July 2021, the Company established its 2021 Stock Option and Grant Plan (the "2021 Plan") which provides for the granting of stock options, restricted and unrestricted stock units and restricted and unrestricted stock awards to employees and consultants of the Company. In connection with the closing of its IPO, on November 14, 2023 the Company's board of directors adopted the 2023 Incentive Award Plan (the "2023 Plan", collectively with the 2021 Plan, the "Plans") which became effective immediately. As a result of the 2023 Plan, the Company may not grant any additional awards under the 2021 Plan. The 2021 Plan will continue to govern outstanding equity awards granted thereunder.

### 2023 Incentive Award Plan

The Company initially reserved 4,212,860 shares of common stock plus the 6,022 remaining shares of common stock available for issuance under the 2021 Plan for issuance under the 2023 Plan. The shares of common stock reserved for issuance as stock options, restricted stock units, stock appreciation rights and restricted stock awards will automatically increase on the first day of January, including January 1, 2024 for a period of up to ten years in an amount equal to 5% of the total number of shares of the Company's capital stock outstanding on the immediately preceding December 31, or a lesser number of shares as determined by the Company's board of directors. On December 31, 2023, there were 3,893,858 shares available for issuance under the 2023 Plan.

Options granted under the 2023 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees and consultants. The exercise price of an ISO and NSO shall not be less than 100% of the fair market value of the shares on the date of grant. The exercise price of an ISO granted to an employee who at the time of grant is a 10% stockholder shall not be less than 110% of the fair market value of the shares on the date of grant with a term not exceeding 5 years. To date, options have a term of 10 years and generally vest over a four-year period.

### Stock options

Stock option activity for year ended December 31, 2023 was as follows:

	Number of Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	167,882	\$ 1.09	9.65	\$ —
Granted	3,928,714	7.64		
Exercised	(27,787)	1.23		
Cancelled and forfeited	(348,354)	5.32		
Outstanding at December 31, 2023	<u>3,720,455</u>	\$ 7.61	9.49	\$ 57,821
Vested and expected to vest, December 31, 2023	<u>3,720,455</u>	\$ 7.61	9.49	\$ 57,821
Exercisable at December 31, 2023	<u>128,968</u>	\$ 4.46	9.13	\$ 2,410

Aggregate intrinsic value in the above table is calculated as the difference between the exercise price of the options and the Company's estimated fair value of its common stock as of December 31, 2023.

The estimated weighted-average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was \$6.10 and \$0.79 per share, respectively. The aggregate intrinsic value of options exercised during the year ended December 31, 2023 was \$0.3 million. No options were exercised during the year ended December 31, 2022. As of December 31, 2023, there was \$19.8 million of unrecognized stock-based compensation related to stock options, which is expected to be recognized over a weighted-average period of 3.3 years.

### Restricted stock awards

The Company has issued restricted stock awards to certain employees, directors and consultants in exchange for cash consideration equal to the fair value of common stock on the grant date. The restricted stock awards are subject to the repurchase right upon termination of services at a repurchase price lower of (i) the fair market value on the date of repurchase or (ii) their original purchase price no later than nine months after such termination. Shares purchased by employees pursuant to restricted stock awards are not deemed, for accounting purposes, to be issued until those shares vest according to their respective vesting schedules. Proceeds received from issuance of restricted stock awards are recorded as a share repurchase liability within accrued expenses and other current liabilities on the balance sheet and reclassified to additional paid-in capital as such awards vest.

In April 2022, certain restricted stock awards were modified to remove their performance conditions which was accounted for as an improbable-to-probable modification. As the Company determined that the service condition for these awards was not substantive, the Company recorded \$0.2 million of stock-based compensation expense equal to the fair value of the modified awards in April 2022.

The following table summarizes the Company's restricted stock activity:

	Number of Awards	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2022	529,110	\$ 0.93
Issued	1,874	3.94
Repurchased	(14,652)	0.63
Vested	(276,633)	1.18
Unvested as of December 31, 2023	239,699	\$ 0.93

The purchase price of the restricted stock awards is the fair value of common stock as determined by the board of directors at the issuance date. The shares generally vest monthly over four years from the grant date.

The Company recorded \$0.1 million and \$0.2 million in share repurchase liability for restricted stock awards in accrued expenses and other current liabilities in the balance sheets as of December 31, 2023 and 2022, respectively.

As of December 31, 2023, unrecognized stock-based compensation expense related to outstanding unvested restricted stock awards was \$0.1 million, which is expected to be recognized over a weighted-average period 2.3 years.

### ***Stock-based compensation expense***

Total stock-based compensation expense recorded in the statements of operations and comprehensive loss was as follows:

	Year ended December 31,	
	2023	2022
	(in thousands)	
General and administrative	\$ 1,965	\$ 217
Research and development	1,362	80
Total stock-based compensation expense	\$ 3,327	\$ 297

The determination of the fair value of share-based payment awards on the date of grant is affected by the stock price, as well as assumptions regarding a number of complex and subjective variables. These variables include expected stock price volatility over the term of the awards, the expected period of time that stock options are expected to be outstanding, risk-free interest rates, and expected dividends. Estimating the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of complex variables. These inputs include:

- Fair Value of Common Stock* – Prior to the IPO, the fair value of the common stock underlying the stock awards was determined by the Company's board of directors. Given the absence of a public trading market, the board of directors considered numerous objective and subjective factors to determine the fair value of the Company's common stock at each meeting at which awards were approved. These factors included, but were not limited to (i) contemporaneous third-party valuations of common stock; (ii) the rights, preferences, and privileges of convertible preferred stock relative to common stock; (iii) the Company's financial condition and operating results; (iv) the conditions of the biotechnology industry and the economy in general, (v) the stock price performance and volatility of comparable public companies; and (vi) the lack of marketability of the Company's common stock. Subsequent to the IPO, the fair value of the common stock underlying stock awards is based on the closing price of the Company's common stock as reported on the date of grant on the Nasdaq Global Select Market.

- *Expected Term* – The expected term assumption represents the weighted-average period that the Company's share-based awards are expected to be outstanding. The Company has opted to use the “simplified method” for estimating the expected term of the options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option. The expected term of restricted stock awards was determined using the vesting term of the award.
- *Expected Volatility* – Because the Company does not have sufficient trading history for its common stock, for all stock options granted to date, the volatility data was estimated based on a study of publicly traded industry peer companies. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size, and financial leverage of potential comparable companies.
- *Expected Dividend* – The Black-Scholes option pricing model calls for a single expected dividend yield as an input. The Company currently have no history or expectation of paying cash dividends on our common stock.
- *Risk-Free Interest Rate* – The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the equity-settled award.

The estimated grant-date fair value of awards granted was calculated based on the following assumptions:

	Year ended December 31,	
	2023	2022
Expected term (in years)	5.2 – 6.4	2.8 – 6.1
Expected volatility	84.6% – 97.7%	84.6% – 89.8%
Expected dividend	—	—
Risk-free interest rate	3.2% – 4.7%	3.0% – 4.7%

### ***Employee Stock Purchase Plan***

On November 14, 2023 the Company's board of directors adopted the 2023 Employee Stock Purchase Plan (the “ESPP”) which became effective immediately. The Company initially reserved 386,725 shares of common stock for purchase under the ESPP. The number of shares of common stock reserved for issuance under the ESPP will automatically increase on the first day of January, including January 1, 2024 for a period of up to ten years in an amount equal to 1% of the total number of shares of the Company’s common stock outstanding on the immediately preceding December 31, or a lesser number of shares determined by the Company’s board of directors; however, no more than 6,561,663 share of common stock may be issued under the ESPP.

Purchases are accomplished through the participation of discrete offering periods. For each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of the fair market value of the Company’s common stock on (1) the first trading day of the applicable offering period or (2) the last trading day of the applicable offering period. There were no shares issued under the ESPP during the year ended December 31, 2023.

## **10. License and research and development agreements**

### ***Stanford license agreement***

In August 2022, the Company entered into a license agreement with the Board of Trustees of the Leland Stanford Junior University (“Stanford University”) relating to the Company’s platform technologies relating to CAR T-cell therapies (the “Stanford License”). Pursuant to the Stanford License, Stanford University granted the Company a worldwide, exclusive license under certain patent rights, and a worldwide non-exclusive license under certain technology, in each case, owned or controlled by Stanford University, to make, use and sell products, methods or services in the field of human therapeutic and diagnostic products. The licensed patent rights cover platform technology relating to the use of CD2/CD58 co-stimulatory signaling in cell therapy.

As consideration for the licenses granted under the Stanford License, the Company made an upfront payment of \$50,000 and issued 67,605 shares of its common stock with a fair value of \$0.1 million, of which 22,317 shares were issued to Stanford University, 27,100 shares were issued to two non-profit organizations that supported the

research, and 18,188 shares were issued to various Stanford University inventors. The Company determined that the purchase of the licenses under the Stanford License represented an asset acquisition as it did not meet the definition of a business. As the acquired licenses represented in-process research and development (“IPR&D”) assets with no alternative future use, the Company recorded the upfront consideration of \$0.2 million as research and development expense in August 2022, upon entering into the Stanford License. The Company recorded research and development expense pursuant to the Stanford License in the amount of \$20,000 and \$0.2 million during the years ended December 31, 2023 and 2022, respectively.

In addition to annual license maintenance fees of up to \$0.1 million per year, the Company may be required to pay up to \$7.5 million for sales milestone payments, up to \$4.0 million in development milestone payments for each product covered by licensed patent rights upon initiation of specific clinical trials or receipt of regulatory approvals, up to \$50,000 in a milestone payment upon achievement of commercial milestone event, up to \$0.5 million in a milestone payment upon achievement of certain additional milestone events, and double-digit percentage milestone payments on the first two licensed non-patent products and, subject to certain royalty reductions, as applicable, low single-digit percentage royalties on net sales of products that are covered by the licensed patent rights or licensed technology. Subject to the terms of the Stanford License, the Company also agreed to pay Stanford University a certain percentage of non-royalty sublicense-related revenue that the Company receives from third-party sublicenses.

Crystal Mackall and Robbie Majzner, who were the Company’s principal owners and directors when the Company entered into the Stanford License, are employees and faculty members leading CAR T-cell therapy research programs at Stanford University.

### ***Oxford license and supply agreement***

In June 2022, the Company entered into a License and Supply Agreement (the “Oxford Agreement”), with Oxford Biomedica (UK) Limited (“Oxford”) for the manufacture and supply of lentiviral vectors for clinical and potentially commercial purposes by the Company. Pursuant to the Oxford Agreement, Oxford granted to the Company a non-exclusive worldwide, sub-licensable, royalty-bearing license under certain intellectual property rights for the purposes of research, development and commercialization of products transduced with the vectors manufactured by Oxford or by the Company following a technology transfer by Oxford, which products are directed against certain initial targets, and upon payment of certain fees, additional targets as agreed by Oxford and the Company.

As consideration for the license granted under the Oxford Agreement, the Company paid an upfront license fee of \$0.2 million. The Company determined that the purchase of the license under the Oxford Agreement represented an asset acquisition as it did not meet the definition of a business. As the acquired license represented IPR&D assets with no alternative future use, the Company recorded the upfront payment of \$0.2 million as research and development expense in June 2022, upon entering into the Oxford Agreement. The Company recorded research and development expense related to the achievement of certain development milestones in the amount of \$0.3 million and \$0.2 million during the years ended December 31, 2023 and 2022, respectively.

The Company may be required to pay up to an aggregate of \$0.3 million of development milestones, \$1.0 million of regulatory milestones and \$8.0 million of commercial milestones for each target if such milestones are achieved by licensed products directed to such target. Additionally, the Company is obligated to pay an earned royalty on net sales of products manufactured with the Oxford vector at a low single-digit percentage.

Unless terminated earlier, the Oxford Agreement will expire when no further payments are due to Oxford. The Company can terminate the agreement at will upon advance written notice and may be subject to certain manufacturing slot cancellation fees.

### ***National Cancer Institute***

In March 2022, the Company entered into an exclusive license agreement (the “2022 NCI License”) with the U.S. Department of Health and Human Services, as represented by The National Cancer Institute (“NCI”), pursuant to which the Company obtained a worldwide, royalty-bearing, exclusive license under certain patent rights to make, use, sell, offer for sale, and import certain autologous products covered by such licensed patents in the field of

CAR-T immunotherapies for the treatment of B-cell malignancies that express CD22, and a non-sublicensable exclusive license to make, use, and import, but not sell, certain allogenic products and to practice processes in the field of certain CAR-T immunotherapies for the treatment of B-cell malignancies that express CD22 for evaluation purposes, with an exclusive option to negotiate a non-exclusive or exclusive commercialization license. The exclusive option can be extended once for one year on payment of an extension royalty of \$50,000.

As consideration for the licenses granted under the 2022 NCI License, the Company is required to pay the NCI a non-refundable license fee of \$0.6 million, of which \$0.2 million was paid in 2022, and \$0.1 million was paid in 2023, and the remaining balance of \$0.3 million is payable in two equal annual installments beginning on the second anniversary of the effective date of the agreement. The Company accrued the non-refundable upfront fees of \$0.4 million upon entering into the 2022 NCI License. As of December 31, 2023 and 2022, \$0.1 million and \$0.1 million, respectively, of non-refundable upfront fees were accrued in accrued expenses and other current liabilities and \$0.2 million and \$0.3 million, respectively, are classified as other non-current liabilities on the balance sheet. The Company determined that the purchase of the license under the 2022 NCI License represented an asset acquisition as it did not meet the definition of a business. As the acquired license represented IPR&D assets with no alternative future use, the Company recorded the initial consideration of \$0.6 million under the 2022 NCI License as research and development expense in March 2022, upon entering into the 2022 NCI License. During the year ended December 31, 2023, the Company recorded research and development expense of \$0.6 million related to the minimum annual royalty and the achievement of certain development milestones.

The Company agreed to pay up to \$0.2 million in regulatory milestone payments upon achieving specific regulatory filings, up to \$1.8 million in development milestone payments upon achieving specific clinical trials or registration trials, and up to \$16.0 million in sales milestones upon achievement of specific commercial milestone events for up to three distinct licensed products, and an earned royalty on net sales of autologous cell therapy products covered by the licensed patent rights and, if the Company chooses to exercise the exclusive option mentioned above, on net sales of allogenic products, at a low single-digit percentage, depending on the amount of annual net sales and subject to the terms of the 2022 NCI License. The Company is also required to make minimum annual royalty payments of \$50,000 per year, which will be creditable against royalties due for sales in that year. In addition, the Company is obligated to pay the NCI a percentage of non-royalty revenue received by the Company from its right to sublicense. Additionally, in the event the Company is granted a priority review voucher (“PRV”), the Company would be obligated to pay the NCI a minimum of \$5.0 million upon the sale, transfer or lease of the PRV or \$0.5 million upon submission of the PRV for use by the U.S. Food and Drug Administration (“FDA”). The Company is also obligated to pay the NCI a royalty based on a percentage of the fair market value of the consideration the Company receives for any assignment of the 2022 NCI License to a non-affiliate (upon the NCI’s prior written consent) or on an allocated portion of the fair value of consideration received in connection with a change in control (including an IPO). On the closing of the Company’s IPO in November 2023, the change in control milestone was met.

The NCI may terminate or modify the 2022 NCI License in the event of an uncured material breach, including, but not limited to, if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NCI.

In February 2023, the Company entered into an exclusive license agreement (the “2023 NCI License”) with the NCI, pursuant to which the Company obtained a worldwide, royalty-bearing, exclusive license under certain patent rights owned by the NCI to make, use, sell and import products and to practice processes in the field of certain CAR-T immunotherapies for the treatment of B-cell malignancies, wherein the T cells are engineered to express CD22 in combination with binders, CARs or other receptors targeting CD19, CD20, and/or CD79b; and at least one of the following: manufacturing the product with the STASH platform technology and/or a technology to activate CD2 signaling in the CAR T cell.

As consideration for the licenses granted under the 2023 NCI License, the Company must pay the NCI a non-refundable license fee of \$0.3 million in three installments whereby the first installment is payable within 60 days of the execution of the agreement and the remaining two payments due on the first and second anniversaries of the effective date of the agreement. Additionally, the Company must reimburse the NCI for \$0.1 million in expenses incurred by the NCI prior to January 1, 2022 related to the preparation, filing, prosecution, and maintenance of all

patent applications and patents included in the license under the 2023 NCI License. The Company determined that the purchase of the license under the 2023 NCI License represented an asset acquisition as it did not meet the definition of a business. As the acquired license represented IPR&D assets with no alternative future use, upon entering the 2023 NCI License in February 2023, the Company recorded the initial consideration of \$0.4 million under the 2023 NCI License, consisting of the non-refundable upfront fees, as research and development expense. The Company accrued these amounts of which \$0.1 million is classified as other non-current liabilities on the balance sheet as of December 31, 2023. During the year ended December 31, 2023, the Company recorded research and development expense of \$0.4 million related to the minimum annual royalty.

The Company agreed to pay up to \$0.1 million in regulatory milestone payments upon making specific regulatory filings, up to \$1.7 million in development milestone payments upon achieving specific clinical trials or registration trials, and up to \$16.0 million in sales milestones upon achievement of specific commercial milestone events. Subject to the terms of the 2023 NCI License, the Company also agreed to pay a low single-digit percentage on earned royalties on net sales of products covered by the licensed patent rights. The Company also agreed to make minimum annual royalty payments of \$50,000 per year, which will be creditable against royalties due for sales in that year. In addition, the Company is obligated to pay the NCI a percentage of non-royalty revenue received by the Company from its right to sublicense at defined percentages. Additionally, if the Company is granted a PRV, the Company would be obligated to pay the NCI a minimum of \$5.0 million upon the sale, transfer or lease of the PRV or \$0.5 million upon submission of the PRV for use by the FDA. The Company is also obligated to pay the NCI a royalty based on a percentage of the fair market value of the consideration the Company receives for any assignment of the 2023 NCI License to a non-affiliate (upon the NCI's prior written consent) or on an allocated portion of the fair value of consideration received in connection with a change in control (including an IPO). On the closing of the Company's IPO in November 2023, the change in control milestone was met.

Unless earlier terminated, the 2023 NCI License will expire upon the expiration of the last to expire licensed patent right. The NCI may terminate or modify the 2023 NCI License in the event of an uncured material breach, including, but not limited to, if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NCI.

In connection with the closing of the Company's IPO in November 2023, the Company accrued a total of \$0.3 million of research and development expense within accrued clinical and research and development expenses on the balance sheet related to the change in control royalty for both the 2022 NCI License and the 2023 NCI License.

## **11. Related parties**

The 2022 Convertible Notes (see Note 7) were issued in part to a related party, a significant investor, for an aggregate principal amount of \$16.0 million. As of December 31, 2022, \$16.4 million in principal and accrued interest was outstanding to the related party. In February 2023, \$18.7 million in principal and accrued interest outstanding to the related party was settled through conversion into 1,833,623 shares of Series A-2 redeemable convertible preferred stock (see Note 6).

Apart from the transactions and balances detailed in Note 6, Note 7 and Note 10, the Company has no other significant or material related party transactions during the years ended December 31, 2023 and 2022.

## **12. Income taxes**

The loss before provision for income taxes for the years ended December 31, 2023 and 2022 is entirely domestic. The Company has no current or deferred income tax expense for federal or state purposes for the years ended December 31, 2023 and 2022.



The reconciliation of the effective tax rate for income taxes from the federal statutory rate were as follows:

	Year ended December 31,	
	2023	2022
U.S. federal taxes at statutory rate	21.0%	21.0%
State tax – net of federal	0.3	(1.8)
Federal tax credits	0.2	7.8
Change in valuation allowance	(19.8)	(23.4)
Stock-based compensation	(0.4)	(0.1)
Non-deductible expenses	(1.3)	(3.2)
Other	-	(0.3)
Total	—%	—%

The income tax effect of temporary differences that give rise to significant portions of the Company’s deferred tax assets at December 31, 2023 and 2022 is presented below:

	December 31,	
	2023	2022
(in thousands)		
Deferred tax assets:		
Depreciation and amortization	\$ —	\$ 1,220
Capitalized research and development costs	17,935	6,009
Net operating loss carryforwards	2,277	1,244
Accrued expenses and other current liabilities	48	97
Operating lease liabilities	6,133	441
Tax credit carryforwards	2,658	2,350
Capitalized startup costs	7,670	—
Stock-based compensation	301	3
Total deferred tax assets	37,022	11,364
Deferred tax liabilities		
Right of use assets	(6,064)	(465)
Fixed assets	(601)	—
Total deferred tax liabilities	(6,665)	(465)
Total net deferred tax assets	30,357	10,899
Less: valuation allowance	(30,357)	(10,899)
Net deferred tax assets	\$ —	\$ —

As of December 31, 2023, the Company has net operating loss carryforwards of approximately \$10.8 million and \$2.3 million available to reduce future taxable income, if any, for Federal and California income tax purposes, respectively. The Federal net operating loss carryforwards do not expire and are limited to 80% of taxable income and California net operating loss carryforwards begin to expire in 2040.

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding realization of such assets. The net increase in the valuation allowance for the years ended December 31, 2023 and 2022 was \$19.5 million and \$9.6 million, respectively. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax-planning strategies in making this assessment. Based on these factors, management has provided a full valuation allowance for its deferred tax assets.

As of December 31, 2023, the Company has Federal and California research and development credit carryforwards of \$2.3 million and \$1.9 million, respectively. The Federal research and development credit carryforwards will expire beginning in 2042 if not utilized. The California research and development credits have no expiration date.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the “IRC”), if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. California has similar rules. The Company conducted a Section 382 study and determined that it has experienced ownership changes in October 2020, February 2021, and February 2023. The ownership changes did not result in a permanent limitation of the pre-change net operating loss and research and development credit carryforwards. In addition, future changes in the Company’s stock ownership, some of which are outside of its control, could result in an additional ownership change under Section 382 of the IRC.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	December 31,	
	2023	2022
	(in thousands)	
Balance at the beginning of the year	\$ 872	\$ 35
Increases based on tax positions related to current year	717	837
Increases based on tax positions related to prior years	62	-
Reductions based on tax positions related to prior years	(417)	-
Balance at end of year	<u>\$ 1,234</u>	<u>\$ 872</u>

As of December 31, 2023, the Company had \$1.2 million of unrecognized tax benefits which are comprised of federal of \$0.8 million and California of \$0.4 million. The Company’s unrecognized gross tax benefits would not reduce its annual effective tax rate if recognized because the Company has recorded a full valuation allowance on deferred tax assets. The Company does not foresee any material changes to its gross unrecognized tax benefit within the next 12 months. The Company recognizes interest and/or penalties related to income tax matters in income tax expense. The Company did not recognize any accrued interest and penalties related to gross unrecognized tax benefits related to the years ended December 31, 2023, and 2022. All years are open for examination by federal and state authorities. The Company currently has no federal or state tax examinations in progress.

### 13. Commitments and Contingencies

#### *Indemnification agreements*

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners, members of its board of directors, officers, and other parties with concerning certain matters, including, but not limited to, losses arising out of breach of such agreements, services to be provided by the Company, negligence or willful misconduct of the Company, violations of law by the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with directors and certain officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise because of their status or service as directors, officers, or employees.

No demands have been made upon the Company to provide indemnification under such agreements, and thus, there are no claims that the Company is aware of that could have a material effect on the Company’s balance sheets, statements of operations and comprehensive loss, or statements of cash flows.

#### *Litigation*

Liabilities for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources are recorded when it is probable that a liability has been incurred and the amount can be reasonably estimated. There are no matters currently outstanding for which any liabilities have been accrued. The Company was not a defendant in any lawsuit for the years ended December 31, 2023 and 2022.

#### 14. Net Loss Per Share

A reconciliation of net loss attributable to common stockholders and the number of shares in the calculation of basic and diluted loss per share was as follows:

	Year ended December 31,	
	2023	2022
(in thousands, except share and per share amounts)		
<b>Numerator:</b>		
Net loss attributable to common stockholders	\$ (98,147)	\$ (40,951)
<b>Denominator:</b>		
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	5,938,782	392,268
Net loss per share attributable to common stockholders, basic and diluted	\$ (16.53)	\$ (104.40)

The following potentially dilutive shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been anti-dilutive (on an as-converted basis):

	December 31,	
	2023	2022
Outstanding stock options	3,720,455	167,882
Restricted stock awards subject to repurchase	239,699	529,110
Convertible preferred stock, as converted	—	810,700
2022 Convertible Notes, as converted	—	2,870,397
Total	3,960,154	4,378,089

#### 15. Subsequent events

##### *Oxford license and supply agreement*

In March 2024, the Company entered into an amendment to the Oxford Agreement to amend the royalty payment structure for vectors manufactured by Oxford. The Company is not obligated to pay royalties on licensed products related to CRG-022 and is obligated to pay an additional target fee of \$0.5 million and earned royalty on net sales of licensed products related to targets other than CRG-022. The Company is obligated to pay reduced regulatory and commercial milestone payments for CRG-022 and is obligated to pay up to \$1.0 million in regulatory milestones for each target (except for CRG-022) if such milestones are achieved for the licensed product.

**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***

As of December 31, 2023, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our 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). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, solely as a result of the material weakness in our internal control over financial reporting described below, as of December 31, 2023, our disclosure controls and procedures were not effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

***Changes in Internal Control over Financial Reporting***

There are no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the year ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control financial reporting.

In preparing the financial statements as of and for the year ended December 31, 2022, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses, which remain unremediated as of December 31, 2023. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified in our internal control over financial reporting related to: (i) an insufficient complement of personnel with an appropriate level of technical knowledge to create the proper environment for effective internal control over financial reporting, (ii) the lack of an effective risk assessment process, (iii) the lack of formalized processes and control activities to support the appropriate segregation of duties over the review of account reconciliations and journal entries and (iv) the lack of monitoring and communication of control processes and relevant accounting policies and procedures.

To remediate these material weaknesses, we are in the process of implementing measures designed to review and document financial processes and controls, formalizing policies and procedures to improve our internal control over financial reporting, as well as hiring of qualified resources to the finance department, including supervisory roles.

While we believe that these efforts will improve our internal control over financial reporting, the design and implementation of our remediation is ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

***Management's Report on Internal Control over Financial Reporting***

The Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

***Attestation Report of Registered Public Accounting Firm***

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for “emerging growth companies.”

***Inherent Limitation on the Effectiveness of Internal Controls and Procedures***

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**Item 9B. Other Information.**

***Insider Trading Arrangements and Policies***

During the fiscal quarter ended December 31, 2023, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

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

None.

## PART III

### **Item 10. Directors, Executive Officers and Corporate Governance.**

#### **Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to all our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on the investor relations section of our website. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website or in public filings.

The information required to be included by Item 10 of Form 10-K will be included in the definitive proxy statement (the “Proxy Statement”) for our 2024 Annual Meeting of Stockholders and such information is incorporated by reference herein. The Proxy Statement will be filed electronically with the SEC within 120 days after the end of the fiscal year covered by this Form 10-K pursuant to Regulation 14A of the Exchange Act.

### **Item 11. Executive Compensation.**

The information required by this item of Form 10-K will be included under the caption “Executive and Director Compensation” in our Proxy Statement and is incorporated by reference herein.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this item of Form 10-K will be included under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Equity Compensation Plans” in our Proxy Statement and is incorporated by reference herein.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this item of Form 10-K will be included under the captions “Certain Relationships and Related Party Transactions” and “Board of Directors and Corporate Governance-Director Independence” in our 2024 Proxy Statement and is incorporated by reference herein.

### **Item 14. Principal Accountant Fees and Services.**

The information required to be included by Item 14 will be included in the Proxy Statement for our 2024 Annual Meeting of Stockholders and such information is incorporated by reference herein.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules.**

The following documents are filed as part of this report:

**1. Financial Statements**

Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

**2. Financial Statement Schedules**

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

**3. Exhibits**

The following is a list of exhibits filed or furnished as part of this Annual Report on Form 10-K.

## Exhibit Index

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	<a href="#">Amended and Restated Certificate of Incorporation, as amended, currently in effect.</a>	8-K	11/14/2023	3.1	
3.2	<a href="#">Bylaws, as amended, currently in effect.</a>	8-K	11/14/2023	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2				X
4.2	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	11/6/2023	4.2	
10.1	<a href="#">Lease Agreement dated December 11, 2023 between ARE-San Francisco No. 63, LLC and CARGO Therapeutics, Inc.</a>				X
10.2#	<a href="#">CARGO Therapeutics, Inc. 2023 Incentive Award Plan</a>	S-8	11/14/2023	99.2(a)	
10.3#	<a href="#">CARGO Therapeutics, Inc. 2023 Employee Stock Purchase Plan</a>	S-8	11/14/2023	99.3	
10.4#	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement Under the 2023 Incentive Award Plan</a>	S-8	11/14/2023	99.2(b)	
10.5#	<a href="#">Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2023 Incentive Award Plan</a>	S-8	11/14/2023	99.2(c)	
10.6#	<a href="#">CARGO Therapeutics, Inc. 2021 Stock Option and Grant Plan and forms of option agreements thereunder</a>	S-1	10/20/2023	10.5(a)	
10.7#	<a href="#">Amendment No. 5 to CARGO Therapeutics, Inc. 2021 Stock Option and Grant Plan</a>	S-1	10/20/2023	10.5(b)	
10.8#	<a href="#">Form Agreements under the CARGO Therapeutics, Inc. 2021 Stock Option and Grant Plan</a>	S-1	10/20/2023	10.5(c)	
10.9†	<a href="#">Exclusive License Agreement effective August 1, 2022, by and between CARGO Therapeutics, Inc. and the Board of Trustees of the Leland Stanford Junior University</a>	S-1	10/20/2023	10.1(a)	
10.10†	<a href="#">Amendment No. 1 to Exclusive License Agreement effective August 1, 2022, by and between CARGO Therapeutics, Inc. and the Board of Trustees of the Leland Stanford Junior University</a>	S-1	10/20/2023	10.1(b)	
10.11	<a href="#">License and Supply Agreement, dated June 24, 2022, by and between CARGO Therapeutics, Inc. and Oxford Biomedica (UK) Limited</a>	S-1/A	11/1/2023	10.2	
10.12	<a href="#">Patent License Agreement, dated March 16, 2022, by and between CARGO Therapeutics, Inc. and the National Cancer Institute.</a>	S-1	10/20/2023	10.3	
10.13	<a href="#">Patent License Agreement, dated February 24, 2023, by and between CARGO Therapeutics, Inc. and the National Cancer Institute.</a>	S-1	10/20/2023	10.4	
10.14#	<a href="#">Employment Agreement by and between CARGO Therapeutics, Inc. and Gina Chapman</a>	S-1	10/20/2023	10.8	
10.15#	<a href="#">Employment Agreement by and between CARGO Therapeutics, Inc. and Anup Radhakrishnan</a>	S-1	10/20/2023	10.9	



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10.16#	<a href="#"><u>Employment Agreement by and between CARGO Therapeutics, Inc. and Shishir Gadam</u></a>	S-1	10/20/2023	10.10	
10.17#	<a href="#"><u>Employment Agreement by and between CARGO Therapeutics, Inc. and Ginna Laport</u></a>	S-1	10/20/2023	10.14	
10.18	<a href="#"><u>Form of Indemnification and Advancement Agreement for directors and officers</u></a>	S-1	10/20/2023	10.12	
10.19	<a href="#"><u>Sublease Agreement, dated November 4, 2021, by and between BigHat Biosciences, Inc. and CARGO Therapeutics, Inc. (f/k/a Syncopation Life Sciences, Inc.)</u></a>	S-1	10/20/2023	10.13(a)	
10.20	<a href="#"><u>First Amendment to Sublease Agreement, dated August 17, 2022, by and between BigHat Biosciences, Inc. and CARGO Therapeutics, Inc. (f/k/a Syncopation Life Sciences, Inc.)</u></a>	S-1	10/20/2023	10.13(b)	
10.21#	<a href="#"><u>Non-Employee Director Compensation Program</u></a>	S-1/A	11/6/2023	10.14	
23.1	<a href="#"><u>Consent of Independent Registered Public Accounting Firm.</u></a>				X
24.1	<a href="#"><u>Power of Attorney (included in the signature page hereto).</u></a>				X
31.1	<a href="#"><u>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.</u></a>				X
31.2	<a href="#"><u>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.</u></a>				X
32.1+	<a href="#"><u>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.</u></a>				X
97	<a href="#"><u>CARGO Therapeutics, Inc. Policy for Recovery of Erroneously Awarded Compensation</u></a>				X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbases Document				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

+ This certification attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

# Indicates management contract or compensatory plan.

† Certain portions of this document constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).

**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.

CARGO Therapeutics, Inc.

Date: March 21, 2024

By: \_\_\_\_\_  
/s/ Gina Chapman  
**Gina Chapman**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

Date: March 21, 2024

By: \_\_\_\_\_  
/s/ Anup Radhakrishnan  
**Anup Radhakrishnan**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Gina Chapman and Anup Radhakrishnan, jointly and severally, as his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and 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 all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitutes or substitute, 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gina Chapman</u> <b>Gina Chapman</b>	Chief Executive Officer and Director (Principal Executive Officer)	March 21, 2024
<u>/s/ Anup Radhakrishnan</u> <b>Anup Radhakrishnan</b>	Chief Financial Officer (Principal Financial Officer)	March 21, 2024
<u>/s/ John Orwin</u> <b>John Orwin</b>	Chairperson and Director	March 21, 2024
<u>/s/ Abraham Bassan</u> <b>Abraham Bassan</b>	Director	March 21, 2024
<u>/s/ Reid Huber</u> <b>Reid Huber</b>	Director	March 21, 2024
<u>/s/ David Lubner</u> <b>David Lubner</b>	Director	March 21, 2024
<u>/s/ Krishnan Viswanadhan</u> <b>Krishnan Viswanadhan</b>	Director	March 21, 2024

## LEASE AGREEMENT

THIS LEASE AGREEMENT (this "**Lease**") is made this 11th day of December, 2023 (the "**Effective Date**"), between **ARE-SAN FRANCISCO NO. 63, LLC**, a Delaware limited liability company ("**Landlord**"), and **CARGO THERAPEUTICS, INC.**, a Delaware corporation ("**Tenant**").

### BASIC LEASE PROVISIONS

**Building:** 835 Industrial Road, San Carlos, California 94070

**Premises:** That portion of the Building, commonly known as Suites 300 and 400, comprised of the entire 3<sup>rd</sup> and 4<sup>th</sup> floor of the Building, containing approximately 99,557 rentable square feet, as determined by Landlord, as shown on **Exhibit A**.

**Project:** The real property on which the Building in which the Premises are located, together with all improvements thereon and appurtenances thereto as described on **Exhibit B**.

**Base Rent:** Initially, \$5.70 per rentable square foot of the Premises per month, subject to adjustment pursuant to Section 4 hereof.

**Rentable Area of Premises:** 99,557 sq. ft.

**Rentable Area of Building:** 248,103 sq. ft.

**Rentable Area of Project:** 522,729 sq. ft.

**Tenant's Share of Operating Expenses of Building:** 40.13%

**Building's Share of Operating Expenses of Project:** 47.46%

**Security Deposit Amount:** \$567,474.90

**Target Commencement Date:** January 1, 2024

**Rent Adjustment Percentage:** 3%

**Base Term:** Beginning on the Commencement Date and ending 87 months from the first day of the first full month following the Commencement Date. For clarity, if the Commencement Date occurs on the first day of a month, the expiration of the Base Term shall be measured from that date. If the Commencement Date occurs on a day other than the first day of a month, the expiration of the Base Term shall be measured from the first day of the following month.

**Permitted Use:** Research and development laboratory, related office and other related uses consistent with the character of the Project and otherwise in compliance with the provisions of Section 7 hereof.

**Address for Rent Payment: Landlord's Notice Address:**

P.O. Box 975383 26 North Euclid Avenue  
Dallas, TX 75397-5383 Pasadena, CA 91101  
Attention: Corporate Secretary  
Email: legalnotice@are.com

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registered trademarks of Alexandria Real Estate Equities, Inc.

<b>Tenant's Notice Address</b>	<b>Tenant's Notice Address</b>
<b>Prior to Commencement Date:</b>	<b>After Commencement Date:</b>
900 Alameda De Las Pulgas, Suite 350, San Mateo, CA 94403 Attention: Haley Gilbert Email: hgilbert@cargo-tx.com and facilities@cargo-tx.com	835 Industrial Road, Suite 300 San Carlos, CA 94070 Attention: Lease Administrator Email: hgilbert@cargo-tx.com and facilities@cargo-tx.com

The following Exhibits and Addenda are attached hereto and incorporated herein by this reference:

- EXHIBIT A** - PREMISES DESCRIPTION       **EXHIBIT B** - DESCRIPTION OF PROJECT
- EXHIBIT C** - WORK LETTER     **EXHIBIT D** - COMMENCEMENT DATE
- EXHIBIT E** - RULES AND REGULATIONS     **EXHIBIT F** - TENANT'S PERSONAL PROPERTY
- EXHIBIT G** – EXISTING FF&E

1. **Lease of Premises.** Upon and subject to all of the terms and conditions hereof, Landlord hereby leases the Premises to Tenant and Tenant hereby leases the Premises from Landlord. The portions of the Project that are for the non-exclusive use of tenants of the Project are collectively referred to herein as the “**Common Areas**.” Subject to the terms and conditions of this Lease, Tenant shall have the appurtenant right to use the Common Areas along with others having the right thereto. The Common Areas shall include, without limitation, any common amenities now or hereafter located in, on or otherwise serving the Project, if any, as may exist from time to time, as determined by Landlord in Landlord’s sole and absolute discretion (each, a “**Project Amenity**” and collectively, the “**Project Amenities**”). Landlord reserves the right to modify the Common Areas, provided that such modifications do not materially adversely affect Tenant’s use of or access to the Premises for the Permitted Use. From and after the Commencement Date through the expiration of the Term (as defined in [Section 2](#)), Tenant shall have access to the Building and the Premises 24 hours a day, 7 days a week, except in the case of emergencies, as the result of Legal Requirements, the performance by Landlord of any installation, maintenance or repairs required or permitted to be performed by Landlord under this Lease, or any other temporary interruptions, and otherwise subject to the terms of this Lease.

2. **Delivery; Acceptance of Premises; Commencement Date.** Landlord shall use reasonable efforts to deliver the Premises to Tenant on or before the Target Commencement Date (“**Delivery**” or “**Deliver**”). If Landlord fails to timely Deliver the Premises, Landlord shall not be liable to Tenant for any loss or damage resulting therefrom, and this Lease shall not be void or voidable except as provided herein. Notwithstanding anything to the contrary contained herein, if Landlord fails to Deliver the Premises to Tenant by the date that is 90 days after the Target Commencement Date (as such date may be extended for delays caused by Tenant or Force Majeure (as defined in [Section 34](#)) delays, the “**Abatement Date**”), then, commencing on the first day immediately following the expiration of the Subsequent Abatement Period (as defined below), Base Rent shall be abated on a day-for-day basis for each day after the Abatement Date that Landlord failed to Deliver the Premises to Tenant. If Landlord does not Deliver the Premises within 180 days of the Target Commencement Date for any reason other than delays caused by Tenant or Force Majeure delays, this Lease may be terminated by Tenant by written notice to Landlord, and if so terminated: (a) the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be returned to Tenant, and (b) neither Landlord nor Tenant shall have any further rights, duties or obligations under this Lease, except with respect to provisions which expressly survive termination of this Lease. If Tenant does not elect to void this Lease within 10 business days of the lapse of such 180 day period (as extended by Force Majeure delays and delays caused by Tenant) such right to void this Lease shall be waived and this Lease shall remain in full force and effect.

The “**Commencement Date**” shall be the date Landlord Delivers the Premises to Tenant. The “**Rent Commencement Date**” shall be 90 days after the Commencement Date. Upon request of Landlord, Tenant shall execute and deliver a written acknowledgment of the Commencement Date, the Rent Commencement Date and the expiration date of the Term when such are established in the form of the



“Acknowledgement of Commencement Date” attached to this Lease as **Exhibit D**; provided, however, Tenant’s failure to execute and deliver such acknowledgment shall not affect Landlord’s rights hereunder. The “**Term**” of this Lease shall be the Base Term, as defined in the Basic Lease Provisions and any Extension Terms which Tenant may exercise pursuant to Section 40 of this Lease.

During the Term, Tenant shall have the right to use all of the furniture, fixtures and equipment located within the Premises as of the Commencement Date (the “**Existing FF&E**”) and identified in further detail on **Exhibit G** attached hereto, at no additional cost or expense to Tenant. Tenant shall have no right to remove any of the Existing FF&E from the Premises without Landlord’s prior written consent and the Existing FF&E shall be returned to Landlord at the expiration or earlier termination of the Term in its the same condition as received, subject to ordinary wear and tear and casualty damage. Prior to the Commencement Date, Landlord shall remove any furniture, fixtures and equipment from the Premises which does not constitute Existing FF&E.

Provided that Tenant has delivered a certificate of insurance reflecting the insurance coverage required to be maintained by Tenant under Section 17, Landlord shall permit Tenant access to the Premises no later than December 1, 2023 for Tenant’s installation and setup of furniture, fixtures and equipment (“**FF&E Installation**”), provided that such FF&E Installation is coordinated with Landlord, and Tenant complies with the terms of this Lease and all other reasonable restrictions and conditions Landlord may reasonably impose. All such access shall be during normal business hours for the Building. Any access to the Premises by Tenant before the Commencement Date shall be subject to all of the terms and conditions of this Lease, excluding the obligation to pay Base Rent or Operating Expenses.

Except as otherwise expressly set forth in this Lease: (A) Tenant shall accept the Premises and the Existing FF&E in their condition existing as of the Commencement Date; (B) Landlord shall have no obligation for any defects in the Premises or the Existing FF&E; and (C) Tenant’s taking possession of the Premises and the Existing FF&E shall be conclusive evidence that Tenant accepts the Premises and the Existing FF&E and that the Premises and the Existing FF&E were in good condition at the time possession was taken. Nothing in this paragraph is intended to limit Landlord’s repair and maintenance obligations under Section 13 of the Lease.

Landlord shall, at its sole cost and expense (which shall not constitute an Operating Expense), be responsible for any repairs to the Building Systems (as defined in Section 13) serving the Premises of which Tenant notifies Landlord in writing within 365 calendar days after the Commencement Date, unless Tenant or any Tenant Party was responsible for the cause of such repair, in which case Tenant shall pay the cost.

Tenant agrees and acknowledges that, except as otherwise expressly set forth in this Lease, neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of all or any portion of the Premises, the Building or the Project, and/or the suitability of the Premises, the Building or the Project for the conduct of Tenant’s business, and Tenant waives any implied warranty that the Premises, the Building or the Project are suitable for the Permitted Use. This Lease constitutes the complete agreement of Landlord and Tenant with respect to the subject matter hereof and supersedes any and all prior representations, inducements, promises, agreements, understandings and negotiations that are not contained herein. Landlord in executing this Lease does so in reliance upon Tenant’s representations, warranties, acknowledgments and agreements contained herein.

### 3. Rent.

(a) **Base Rent.** Tenant shall deliver to Landlord, concurrent with Tenant’s delivery of an executed copy of this Lease to Landlord, the Base Rent due for the calendar month in which the day immediately following the expiration of the Subsequent Abatement Period occurs (or, if such date does not occur on the first day of a calendar month, Base Rent for the first full calendar month following the date in which the day immediately following the expiration of the Subsequent Abatement Period occurs). Tenant shall pay to Landlord in advance, without demand, abatement, deduction or set-off, monthly installments of Base Rent on or before the first day of each calendar month during the Term hereof after the expiration of



the Subsequent Abatement Period, in lawful currency of the United States of America, to the physical address designated by Landlord or by federally insured electronic fund transfer (“EFT”) via wire, Society for Worldwide Interbank Financial Communications (SWIFT) or automated clearing house (ACH) pursuant to the instructions provided by Landlord to Tenant (the “EFT Payment Instructions”). All EFT payments made by Tenant pursuant to this Section 3(a) must include a reference to ARE-San Francisco No. 63, LLC as well as the address of the Building (i.e., 835 Industrial Rd.). Payments of Base Rent for any fractional calendar month shall be prorated. Notwithstanding anything to the contrary contained herein, if the expiration of the Subsequent Abatement Period occurs on a day other than the first day of a calendar month, then Tenant shall pay to Landlord the prorated Base Rent for such partial month on the day immediately following the expiration of the Subsequent Abatement Period and the prepaid Base Rent delivered by Tenant pursuant to this first sentence of this Section 3(a) shall be applied to the first full calendar month following the expiration of the Subsequent Abatement Period. The obligation of Tenant to pay Base Rent and other sums to Landlord and the obligations of Landlord under this Lease are independent obligations. Tenant shall have no right at any time to abate, reduce, or set-off any Rent (as defined in Section 5) due hereunder except for any abatement as may be expressly provided in this Lease.

Notwithstanding anything to the contrary contained herein, so long as Tenant is not then in Default under this Lease, Tenant shall not be required to pay Base Rent for the period commencing on the Rent Commencement Date through the date that is 365 days after the Rent Commencement Date (the “Subsequent Abatement Period”). Tenant shall commence paying full Base Rent on the day immediately following the expiration of the Subsequent Abatement Period. For the avoidance of doubt, Tenant shall be required to pay Operating Expenses and all other amounts payable under the Lease during the Subsequent Abatement Period.

(b) **Additional Rent.** In addition to Base Rent, Tenant agrees to pay to Landlord as additional rent (“Additional Rent”): (i) Tenant’s Share of “Operating Expenses” (as defined in Section 5) as provided in Section 5, and (ii) any and all other amounts Tenant assumes or agrees to pay under the provisions of this Lease, including, without limitation, any and all other sums that may become due by reason of any failure to comply with the agreements, terms, covenants and conditions of this Lease to be performed by Tenant, after any applicable notice and cure period. Tenant shall pay to Landlord any and all Additional Rent due hereunder by EFT in accordance with the EFT Payment Instructions. All EFT payments made by Tenant pursuant to this Section 3(b) must include a reference to ARE-San Francisco No. 63, LLC as well as the address of the Building (i.e., 835 Industrial Rd.)

4. **Adjustments.** Base Rent shall be increased on each annual anniversary of the Rent Commencement Date (provided, however, that if the Rent Commencement Date occurs on a day other than the first day of a calendar month, then Base Rent shall be increased on each annual anniversary of the first day of the first full calendar month immediately following the Rent Commencement Date) (each an “Adjustment Date”) by multiplying the Base Rent payable immediately before such Adjustment Date by the Rent Adjustment Percentage and adding the resulting amount to the Base Rent payable immediately before such Adjustment Date. Base Rent, as so adjusted, shall thereafter be due as provided herein. Base Rent adjustments for any fractional calendar month shall be prorated.

#### 5. Operating Expense Payments.

(a) Landlord shall deliver to Tenant a written estimate of Operating Expenses for each calendar year during the Term (the “Annual Estimate”), which may be revised by Landlord from time to time during such calendar year. Commencing on the Rent Commencement Date, and continuing thereafter on the first day of each calendar month during the Term, Tenant shall pay Landlord an amount equal to 1/12th of Tenant’s Share of the Annual Estimate. Payments for any fractional calendar month shall be prorated.

(b) The term “Operating Expenses” means all costs and expenses of any kind or description whatsoever incurred or accrued each calendar year by Landlord with respect to the Building (including the Building’s Share of all costs and expenses of any kind or description incurred or accrued by Landlord with





respect to the Project) including, without limitation, (1) Taxes (as defined in Section 9), (2) the cost of upgrades to the Building or Project or enhanced services provided at the Building and/or Project which are intended to encourage social distancing, promote and protect health and physical well-being and/or intended to limit the spread of Infectious Conditions (as defined in Section 26), (3) the cost of the Project Amenities (including, without limitation, reimbursement by Landlord to affiliates of Landlord for market rent paid by such affiliates to Landlord for Project Amenities space, commercially reasonable reduced rent, commercially reasonable subsidies or other commercially reasonable concessions which Landlord may provide in connection with the Project Amenities), (4) transportation services (including costs associated with Landlord's operation of or participation in a shuttle service, if any), (5) the cost of repairs, improvements and replacements, provided that to the extent that such repairs, improvements and/or replacements are reasonably determined by Landlord in accordance with sound real estate accounting principles to be capital in nature (each, a "Capital Expenditure"), such costs shall be amortized over the lesser of 10 years and the useful life of such Capital Expenditure with interest at 8.5% per annum, and (6) the costs of Landlord's third party property manager or, if there is no third party property manager, administration rent in the amount of 3% of Base Rent (provided, however, that during the Subsequent Abatement Period, Tenant shall be required to pay administration rent each month equal to the amount of the administration rent that Tenant would have been required to pay in the absence of there being a Subsequent Abatement Period), excluding only:

- (i) the original construction costs of the Project and renovation prior to the Commencement Date and costs of correcting defects in such original construction or renovation;
- (ii) capital expenditures for expansion of the Project;
- (iii) interest, principal payments of Mortgage (as defined in Section 27) debts of Landlord, financing costs and amortization of funds borrowed by Landlord, whether secured or unsecured;
- (iv) depreciation of the Project (except for Capital Expenditures, the cost of which are includable in Operating Expenses);
- (v) advertising, legal and space planning expenses and leasing commissions and other costs and expenses incurred in procuring and leasing space to tenants for the Project, including any leasing office maintained in the Project, free rent and construction allowances for tenants;
- (vi) legal and other expenses incurred in the negotiation or enforcement of leases;
- (vii) completing, fixturing, improving, renovating, painting, redecorating or other work, which Landlord pays for or performs for other tenants within their premises, and costs of correcting defects in such work;
- (viii) costs to be reimbursed by other tenants of the Project or Taxes to be paid directly by Tenant or other tenants of the Project, whether or not actually paid;
- (ix) salaries, wages, benefits and other compensation paid to officers and employees of Landlord who are not assigned in whole or in part to the operation, management, maintenance or repair of the Project;
- (x) costs incurred for off-site offices or facilities maintained in connection with the management, operation, engineering, sustainability, Utility and/or security services provided to the Project and other properties owned by Landlord or affiliates of Landlord, except to the extent of the Project's share of such costs as proportionately allocated among the Project and such other properties owned by Landlord or affiliates of Landlord served by such off-site offices or facilities;

- (xi) general organizational, administrative and overhead costs relating to maintaining Landlord's existence, either as a corporation, partnership, or other entity, including general corporate, legal and accounting expenses;
- (xii) costs (including attorneys' fees and costs of settlement, judgments and payments in lieu thereof) incurred in connection with disputes with tenants, other occupants, or prospective tenants, and costs and expenses, including legal fees, incurred in connection with negotiations or disputes with employees, consultants, management agents, leasing agents, purchasers or mortgagees of the Building;
- (xiii) costs incurred by Landlord due to the violation by Landlord, its employees, agents or contractors or any tenant of the terms and conditions of any lease of space in the Project or any Legal Requirement (as defined in Section 7);
- (xiv) penalties, fines or interest incurred as a result of Landlord's inability or failure to make payment of Taxes and/or to file any tax or informational returns when due, or from Landlord's failure to make any payment of Taxes required to be made by Landlord hereunder before delinquency;
- (xv) overhead and profit increment paid to Landlord or to subsidiaries or affiliates of Landlord for goods and/or services in or to the Project to the extent the same exceeds the costs of such goods and/or services rendered by unaffiliated third parties on a competitive basis;
- (xvi) costs of Landlord's charitable or political contributions, or of fine art maintained at the Project;
- (xvii) costs in connection with services or items which are not available to all tenants of the Project and which are not available to Tenant without specific charges therefor, but which are provided to another tenant or occupant of the Project, whether or not such other tenant or occupant is specifically charged therefor by Landlord;
- (xviii) costs incurred in the sale or refinancing of the Project;
- (xix) net income taxes of Landlord or the owner of any interest in the Project or franchise, capital stock, gift, estate or inheritance taxes or any federal, state or local documentary taxes imposed against the Project or any portion thereof or interest therein (except to the extent such taxes are in substitution for any Taxes payable hereunder);
- (xx) costs arising from the gross negligence or willful misconduct of Landlord or its agents, and employees;
- (xxi) any costs to remove, study, test or remediate, or otherwise related to the presence of Hazardous Materials in or about the Building or the Project for which Tenant is not responsible under this Lease;
- (xxii) any item that, if included in Operating Expenses, would involve a double collection for such item by Landlord; and
- (xxiii) any expenses otherwise includable within Operating Expenses to the extent actually reimbursed by persons other than tenants of the Project under leases for space in the Project.

For the avoidance of doubt, Tenant shall not be obligated to pay any Operating Expenses prior to the Rent Commencement Date. In addition, notwithstanding anything to the contrary contained in this Lease, Operating Expenses incurred or accrued by Landlord with respect to any Capital Expenditures that

are reasonably expected by Landlord to reduce overall Operating Expenses (for example, without limitation, by reducing energy usage at the Project) (the “**Energy Savings Costs**”) shall be amortized over a period of years equal to the least of (A) 10 years, (B) the useful life of such Capital Expenditures, and (C) the quotient of (i) the Energy Savings Costs, divided by (ii) the annual amount of Operating Expenses reasonably expected by Landlord to be saved as a result of such Capital Expenditures.

(c) Within 90 days after the end of each calendar year (or such longer period as may be reasonably required), Landlord shall furnish to Tenant a statement for the previous calendar year (an “**Annual Statement**”) showing in reasonable detail: (i) the total Operating Expenses, (ii) Tenant’s Share of Operating Expenses, and (iii) the total amount of Operating Expenses actually paid by Tenant. If Tenant’s Share of Operating Expenses for such calendar year exceeds the total amount of Operating Expenses actually paid by Tenant for such calendar year, then the excess shall be due and payable by Tenant as Rent within 30 days after delivery of such Annual Statement to Tenant. If the total amount of Operating Expenses actually paid by Tenant for such calendar year exceeds the amount of Tenant’s Share of Operating Expenses for such calendar year, then Landlord shall pay the excess to Tenant within 30 days after delivery of such Annual Statement, except that after the expiration or earlier termination of the Term, or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord. Landlord’s and Tenant’s obligations to pay any overpayments or deficiencies due pursuant to this paragraph shall survive the expiration or earlier termination of this Lease.

(d) The Annual Statement shall be final and binding upon Tenant unless Tenant, within 60 days after Landlord’s delivery to Tenant of the Annual Statement, shall contest any item therein by giving written notice to Landlord, specifying each item contested and the reason therefor. If, during such 60 day period, Tenant reasonably and in good faith questions or contests the accuracy of Landlord’s statement of Tenant’s Share of Operating Expenses, Landlord will provide Tenant with access to Landlord’s books and records relating to the operation of the Project and such information as Landlord reasonably determines to be responsive to Tenant’s questions (the “**Expense Information**”). If after Tenant’s review of such Expense Information, Landlord and Tenant cannot agree upon the amount of Tenant’s Share of Operating Expenses, then Tenant shall have the right to have a regionally or nationally recognized independent public accounting firm selected by Tenant and approved by Landlord (which approval shall not be unreasonably withheld, conditioned or delayed), working pursuant to a fee arrangement other than a contingent fee (at Tenant’s sole cost and expense), audit and/or review the Expense Information for the calendar year in question (the “**Independent Review**”). The results of any such Independent Review shall be binding on Landlord and Tenant. If the Independent Review shows that the payments actually made by Tenant with respect to Operating Expenses for the calendar year in question exceeded Tenant’s Share of Operating Expenses for such calendar year, Landlord shall at Landlord’s option either (i) credit the excess amount to the next succeeding installments of estimated Operating Expenses or (ii) pay the excess to Tenant within 30 days after delivery of such statement, except that after the expiration or earlier termination of this Lease or if Tenant is delinquent in its obligation to pay Rent, Landlord shall pay the excess to Tenant after deducting all other amounts due Landlord. If the Independent Review shows that Tenant’s payments with respect to Operating Expenses for such calendar year were less than Tenant’s Share of Operating Expenses for the calendar year, Tenant shall pay the deficiency to Landlord within 30 days after delivery of such statement. If the Independent Review shows that Tenant has overpaid with respect to Operating Expenses by more than 5% then Landlord shall reimburse Tenant for all actual, out-of-pocket costs incurred by Tenant for the Independent Review. Tenant shall not disclose the results of any Independent Review to any third parties; provided, however, that Tenant may disclose such information to Tenant’s employees, attorneys and accountants in connection with Tenant’s business at the Premises or if required in connection with any dispute resolution proceeding between Landlord and Tenant.

(e) Operating Expenses for the calendar years in which Tenant’s obligation to share therein begins and ends shall be prorated. Notwithstanding anything set forth herein to the contrary, if the Building is not at least 95% occupied on average during any year of the Term, Tenant’s Share of Operating Expenses for such year shall be computed as though the Building had been 95% occupied on average during such year.



(f) “**Tenant’s Share**” shall be the percentage set forth on the first page of this Lease as “Tenant’s Share of Operating Expenses of Building,” and “**Building’s Share**” shall be the percentage set forth on the first page of this Lease as “Building’s Share of Operating Expenses of Project,” each as may be reasonably adjusted by Landlord for changes in the physical size of the Building and/or Project occurring thereafter. The rentable area of the Premises shall not be subject to re-measurement by either party during the Term. Landlord may equitably increase Tenant’s Share for any Operating Expenses that relate to any item of expense or cost (1) equitably and reasonably allocated only to the Premises or the Building, (2) equitably and reasonably allocated to only a portion of the Building or Project that includes the Premises, or (3) a greater proportion of which is equitably and reasonably allocated to the Premises, or a portion of the Building or Project that includes the Premises, as reasonably determined by Landlord. Landlord may equitably increase the Building’s Share for any Operating Expenses that relate to any items of expense or cost (A) equitably and reasonably allocated to only the Building or a portion of the Project that includes the Building, or (B) a greater proportion of which is equitably and reasonably allocated to the Building or a portion of the Project that includes the Building, as reasonably determined by Landlord. Base Rent, Tenant’s Share of Operating Expenses and all other amounts payable by Tenant to Landlord hereunder are collectively referred to herein as “**Rent**.”

6. **Security Deposit.** Within 10 days after the mutual execution and delivery of this Lease by the parties, Tenant shall deliver to Landlord a security deposit (the “**Security Deposit**”) for the performance of all of Tenant’s obligations hereunder in the Security Deposit Amount set forth in the Basic Lease Provisions, which Security Deposit shall be in the form of an unconditional and irrevocable letter of credit (the “**Letter of Credit**”): (i) in form and substance reasonably satisfactory to Landlord, (ii) naming Landlord as beneficiary, (iii) expressly allowing Landlord to draw upon it at any time from time to time by delivering to the issuer notice that Landlord is entitled to draw thereunder, (iv) issued by an FDIC-insured financial institution reasonably satisfactory to Landlord, and (v) redeemable by presentation of a sight draft in the state of Landlord’s choice, or by facsimile or overnight guaranty courier. The Security Deposit shall be held by Landlord as security for the performance of Tenant’s obligations under this Lease. The Security Deposit is not an advance rental deposit or a measure of Landlord’s damages in case of Tenant’s default. Upon each occurrence of a Default (as defined in [Section 20](#)), Landlord may use all or any part of the Security Deposit to pay delinquent payments due under this Lease, future rent damages under California Civil Code Section 1951.2, and the cost of any damage, injury, expense or liability caused by such Default, without prejudice to any other remedy provided herein or provided by law. Landlord’s right to use the Security Deposit under this [Section 6](#) includes the right to use the Security Deposit to pay future rent damages following the termination of this Lease pursuant to [Section 21\(c\)](#) below. Upon any draw down on the Letter of Credit pursuant to this paragraph, Tenant shall deliver to Landlord, within 7 business days after written demand from Landlord, a new Letter of Credit complying with all of the requirements hereof (a “**Replacement Letter of Credit**”) for the full Security Deposit Amount set forth in the Basic Lease Provisions. Tenant hereby waives the provisions of any law, now or hereafter in force, including, without limitation, California Civil Code Section 1950.7, which provide that Landlord may claim from a security deposit only those sums reasonably necessary to remedy defaults in the payment of Rent, to repair damage caused by Tenant or to clean the Premises, it being agreed that Landlord may, in addition, claim those sums reasonably necessary to compensate Landlord for any other loss or damage, foreseeable or unforeseeable, caused by the act or omission of Tenant or any officer, employee, agent or invitee of Tenant. Landlord’s obligation respecting the Security Deposit is that of a debtor, not a trustee, and no interest shall accrue thereon. Upon bankruptcy or other debtor-creditor proceedings against Tenant, the Security Deposit shall be deemed to be applied first to the payment of Rent and other charges due Landlord for periods prior to the filing of such proceedings. If Tenant shall fully perform every provision of this Lease to be performed by Tenant, the Security Deposit, or any balance thereof (i.e., after deducting therefrom all amounts to which Landlord is entitled under the provisions of this Lease), shall be returned to Tenant (or, at Landlord’s option, to the last assignee of Tenant’s interest hereunder) within 90 days after the expiration or earlier termination of this Lease.

Tenant shall deliver a Replacement Letter of Credit to Landlord at least 5 days before the stated expiration date of any then current Letter of Credit for the full Security Deposit Amount set forth in the Basic Lease Provisions. If Tenant does not provide Landlord with a Replacement Letter of Credit as required



pursuant to the immediately preceding sentence, Landlord shall have the right to draw the full amount of the current Letter of Credit and hold the funds drawn in cash without obligation for interest thereon as the Security Deposit until Tenant delivers a Replacement Letter of Credit to Landlord, at which time Landlord shall refund to Tenant the amount of the cash Security Deposit to Tenant less any amount applied under this Lease.

If at any time during the Term the issuer of the Letter of Credit is declared insolvent or is placed into receivership by the FDIC or any other Governmental Authority, or if the issuer is downgraded by S&P/Moody's (if the issuer is credit-rated) or the issuer's 5-year Credit Default Swap spread (as quoted, and if available on Bloomberg Professional Services) goes above 250 bps at any point during the Term, then following the delivery of written notice from Landlord to Tenant, (x) Landlord shall have the right to immediately draw the full amount of the existing Letter of Credit and hold the funds drawn in cash without obligation for interest thereon as the Security Deposit, and (y) Tenant shall have 30 days to deliver a Replacement Letter of Credit to Landlord. If Landlord is unable to draw on the existing Letter of Credit as provide for in clause (x) above then, within 5 business days after Landlord's delivery of written request to Tenant, Tenant shall deliver to Landlord cash in the Security Deposit Amount set forth in the Basic Lease Provisions as an interim Security Deposit until such time as Tenant delivers a Replacement Letter of Credit to Landlord. Upon Tenant's delivery of a Replacement Letter of Credit to Landlord, Landlord shall refund to Tenant the amount of the cash Security Deposit to Tenant less any amount applied under this Lease.

If Landlord transfers its interest in the Project or this Lease, Landlord shall transfer any Security Deposit then held by Landlord to such transferee of Landlord's interest. Upon such transfer, Landlord shall have no further obligation with respect to the Security Deposit, and Tenant's right to the return of the Security Deposit shall apply solely against Landlord's transferee.

## 7. Use.

(a) **Generally.** The Premises shall be used solely for the Permitted Use set forth in the Basic Lease Provisions, and in compliance with all laws, orders, judgments, ordinances, regulations, codes, directives, permits, licenses, covenants and restrictions now or hereafter applicable to the Premises, and to the use and occupancy of the Premises, including, without limitation, the Americans With Disabilities Act, 42 U.S.C. § 12101, et seq. (together with the regulations promulgated pursuant thereto, "ADA") (collectively, "Legal Requirements" and each, a "Legal Requirement"). Tenant shall, upon 5 business days' written notice from Landlord, discontinue any use of the Premises that is declared, in writing, by any Governmental Authority (as defined in Section 9) having jurisdiction to be a violation of a Legal Requirement. Tenant will not use or permit the Premises to be used for any purpose or in any manner that would void Tenant's or Landlord's insurance, increase the insurance risk, or cause the disallowance of any sprinkler or other credits. Tenant shall reimburse Landlord promptly upon demand for any additional premium charged for any such insurance policy by reason of Tenant's failure to comply with the provisions of this Section 7. Tenant shall not permit any part of the Premises to be used as a "place of public accommodation", as defined in the ADA or any similar Legal Requirement. Tenant will use the Premises in a careful, safe and proper manner and will not commit or permit waste, overload the floor or structure of the Premises, subject the Premises to use that would damage the Premises or obstruct or interfere with the rights of Landlord or other tenants or occupants of the Project. In no event shall Tenant conduct any auction, liquidation, or going out of business sale on the Premises, or use or allow the Premises to be used for any unlawful purpose. Tenant shall cause any equipment or machinery to be installed in the Premises so as to reasonably prevent sounds or vibrations from the Premises from extending into Common Areas, or other space in the Project. Tenant shall not place any machinery or equipment which would overload the floor in or upon the Premises or transport or move such items through the Common Areas of the Project or in the Project elevators without the prior written consent of Landlord, which shall not be unreasonably withheld, conditioned or delayed. Tenant shall not, without the prior written consent of Landlord, use the Premises in any manner that will require ventilation, air exchange, heating, gas, steam, electricity or water beyond the existing capacity of the Project as proportionately allocated to the Premises based upon Tenant's Share as usually furnished for the Permitted Use.

(b) **Compliance.** Landlord shall be responsible, at Landlord's cost (i) for the compliance of the Premises with Legal Requirements (including the ADA) as of the Commencement Date, and (ii) for the compliance of the Common Areas of the Project with Legal Requirements (including the ADA) as of the Commencement Date. Following the Commencement Date, Landlord shall make any alterations or modifications to the Common Areas or the exterior of the Building that are required by Legal Requirements and the cost of such alterations or modifications shall (x) constitute an Operating Expense (to the extent such Legal Requirement is generally applicable to similar buildings in the area in which the Project is located), or (y) be at Tenant's expense (to the extent such Legal Requirement is triggered by reason of Tenant's, as compared to other tenants of the Project, particular use of the Premises or Alterations (as defined in Section 12 below)). Except as otherwise expressly provided in the 2 immediately preceding sentences, Tenant, at its sole expense, shall make any alterations or modifications to the Premises that are required by Legal Requirements (including, without limitation, compliance of the Premises with the ADA) related to Tenant's use or occupancy of the Premises and any Alterations. Notwithstanding any other provision herein to the contrary, Tenant shall be responsible for any and all Claims (as defined in Section 16) arising out of or in connection with Legal Requirements, and Tenant shall indemnify, defend, hold and save Landlord harmless from and against any and all Claims arising out of or in connection with any failure of the Premises to comply with any Legal Requirement.

(c) **Sustainability.** Tenant acknowledges that Landlord may, but shall not be obligated to, seek to obtain Leadership in Energy and Environmental Design (LEED), WELL Building Standard, or other similar "green" certification with respect to the Project and/or the Premises, and Tenant agrees, at no material cost to Tenant, to reasonably cooperate with Landlord, and to provide such information and/or documentation as Landlord may reasonably request, in connection therewith.

8. **Holding Over.** If Tenant remains in possession of the Premises after the expiration or earlier termination of the Term without the express written consent of Landlord, (a) Tenant shall become a tenant at sufferance upon the terms of this Lease except that the monthly rental shall be equal to (i) 150% of Base Rent in effect during the last 30 days of the Term, plus (ii) Tenant's Share of Operating Expenses, plus (iii) all other amounts payable by Tenant under this Lease, and (b) Tenant shall be responsible for all damages suffered by Landlord resulting from or occasioned by Tenant's holding over including, without limitation, consequential damages. No holding over by Tenant, whether with or without consent of Landlord, shall operate to extend this Lease except as otherwise expressly provided, and this Section 8 shall not be construed as consent for Tenant to retain possession of the Premises. Acceptance by Landlord of Rent after the expiration of the Term or earlier termination of this Lease shall not result in a renewal or reinstatement of this Lease.

9. **Taxes.** Landlord shall pay, as part of Operating Expenses, all taxes, levies, fees, assessments and governmental charges of any kind, existing as of the Commencement Date or thereafter enacted (collectively referred to as "**Taxes**"), imposed by any federal, state, regional, municipal, local or other governmental authority or agency, including, without limitation, quasi-public agencies (collectively, "**Governmental Authority**") during the Term, including, without limitation, all Taxes: (a) imposed on or measured by or based, in whole or in part, on rent payable to (or gross receipts received by) Landlord under this Lease and/or from the rental by Landlord of the Project or any portion thereof, or (b) based on the square footage, assessed value or other measure or evaluation of any kind of the Premises or the Project, or (c) assessed or imposed by or on the operation or maintenance of any portion of the Premises or the Project, including parking, or (d) assessed or imposed by, or at the direction of, or resulting from Legal Requirements, or interpretations thereof, promulgated by any Governmental Authority, or (e) imposed as a license or other fee, charge, tax, or assessment on Landlord's business or occupation of leasing space in the Project. Landlord may contest by appropriate legal proceedings the amount, validity, or application of any Taxes or liens securing Taxes. If any such Taxes are levied or assessed directly against Tenant, then Tenant shall be responsible for and shall pay the same at such times and in such manner as the taxing authority shall require. Tenant shall pay, prior to delinquency, any and all Taxes levied or assessed against any personal property or trade fixtures placed by Tenant in the Premises, whether levied or assessed against Landlord or Tenant. If any Taxes on Tenant's personal property or trade fixtures are levied against Landlord or Landlord's property, or if the assessed valuation of the Project is increased by a value



attributable to improvements in or alterations to the Premises, whether owned by Landlord or Tenant and regardless of whether such improvements or alterations are affixed to the real property so as to become a part thereof, higher than the base valuation on which Landlord from time-to-time allocates Taxes to all tenants in the Project, Landlord shall have the right, but not the obligation, to pay such Taxes. Landlord's determination of any excess assessed valuation shall be binding and conclusive, absent manifest error. The amount of any such payment by Landlord shall constitute Additional Rent due from Tenant to Landlord within 30 days after Landlord's written demand. Taxes shall not include (a) any net income taxes of Landlord or the owner of any interest in the Project or franchise, capital stock, gift, estate or inheritance taxes or any federal, state or local documentary taxes imposed against the Project or any portion thereof or interest therein (except to the extent such taxes are in substitution for any Taxes payable hereunder), or (b) any penalties, fines or interest incurred as a result of Landlord's inability or failure to make payment of Taxes and/or to file any tax or informational returns when due, or from Landlord's failure to make any payment of Taxes required to be made by Landlord hereunder before delinquency.

**10. Parking.** Subject to all applicable Legal Requirements, Force Majeure, a Taking (as defined in Section 19 below) and the exercise by Landlord of its rights hereunder, Tenant shall have the right, in common with other tenants of the Project pro rata in accordance with the rentable area of the Premises and the rentable areas of the Project occupied by such other tenants, to park in those areas designated for non-reserved parking, subject in each case to Landlord's rules and regulations. As of the Commencement Date, Tenant's pro rata share of parking shall be approximately 2.6 parking spaces per 1,000 rentable square feet of the Premises. Landlord shall not be responsible for enforcing Tenant's parking rights against any third parties, including other tenants of the Project.

**11. Utilities; Services.**

(a) **Generally.** Landlord shall provide or cause to be provided to the Premises, subject to the terms of this Section 11, (i) water, (ii) electricity (including lights and plugs), (iii) heat, ventilation and air conditioning (collectively, "**HVAC**"), (iv) power, and (v) sewer (collectively, "**Utilities**"). Landlord shall pay, as Operating Expenses or subject to Tenant's direct reimbursement obligation as provided for below, for all Utilities used on the Premises, all maintenance charges for Utilities, and any storm sewer charges or other similar charges for Utilities imposed by any Governmental Authority or Utility provider, and any Taxes, penalties, surcharges or similar charges thereon. Landlord may cause, at Landlord's expense (except to the extent necessary as a result of Tenant's disproportionate use of Utilities in which case Tenant shall pay the cost), any Utilities to be separately metered with respect to the Premises or charged directly to Tenant by the provider with respect to Tenant's use in the Premises. Tenant shall pay directly to the Utility provider, prior to delinquency, any separately metered Utilities and services (which may include, among other Utilities and services, telephone and internet service) which may be furnished to Tenant or the Premises during the Term. Tenant shall pay, as part of Operating Expenses, its share of all charges for jointly metered Utilities based upon consumption, as reasonably determined by Landlord. No interruption or failure of Utilities from any cause whatsoever shall result in eviction or constructive eviction of Tenant, termination of this Lease or, except as otherwise provided in the immediately following paragraph, the abatement of Rent. Tenant agrees to limit use of water and sewer with respect to Common Areas to normal restroom use.

Notwithstanding anything to the contrary set forth herein, if (i) a stoppage of a Utility Service (as defined below) to the Premises shall occur and such stoppage is due solely to the gross negligence or willful misconduct of Landlord and not due in any part to any act or omission on the part of Tenant or any Tenant Party or any matter beyond Landlord's reasonable control (any such stoppage of a Utility Service being hereinafter referred to as a "**Service Interruption**"), and (ii) such Service Interruption continues for more than 5 consecutive business days after Landlord shall have received written notice thereof from Tenant, and (iii) as a result of such Service Interruption, the conduct of Tenant's normal operations in the Premises are materially and adversely affected, then there shall be an abatement of one day's Base Rent for each day during which such Service Interruption continues after such 5 business day period; provided, however, that if any part of the Premises is reasonably useable for Tenant's normal business operations or if Tenant conducts all or any part of its operations in any portion of the Premises notwithstanding such Service Interruption, then the amount of each daily abatement of Base Rent shall only be proportionate to



the nature and extent of the interruption of Tenant's normal operations or ability to use the Premises. The rights granted to Tenant under this paragraph shall be Tenant's sole and exclusive remedy resulting from a failure of Landlord to provide services, and Landlord shall not otherwise be liable for any loss or damage suffered or sustained by Tenant resulting from any failure or cessation of services. For purposes hereof, the term "**Utility Service**" shall mean the following services: HVAC service, water, sewer and electricity, but in each case only to the extent that Landlord has an obligation to provide same to Tenant under this Lease.

(b) **Janitorial Services.** Landlord shall, as part of Operating Expenses, provide or cause to be provided with respect to the Common Areas only, refuse and trash collection and janitorial services. Tenant shall be responsible for contracting directly with a vendor reasonably acceptable to Landlord and paying for its own janitorial services for the Premises.

(c) **Emergency Generator.** Landlord's sole obligation for either providing emergency generators or providing emergency back-up power to Tenant shall be: (i) to provide emergency generators with not less than the capacity of the emergency generators located in the Building as of the Commencement Date, and (ii) to contract with a third party to maintain the emergency generators as per the manufacturer's standard maintenance guidelines. Except as otherwise provided in the immediately preceding sentence, Landlord shall have no obligation to provide Tenant with operational emergency generators or back-up power or to supervise, oversee or confirm that the third party maintaining the emergency generators is maintaining the generators as per the manufacturer's standard guidelines or otherwise. Notwithstanding anything to the contrary contained herein, Landlord shall, at least once per calendar quarter as part of the maintenance of the Building, run the emergency generator for a period reasonably determined by Landlord for the purpose of determining whether it operates when started. Landlord shall, upon written request from Tenant (not more frequently than once per calendar year), make available for Tenant's inspection the maintenance contract and maintenance records for the emergency generators for the 12 month period immediately preceding Landlord's receipt of Tenant's written request. During any period of replacement, repair or maintenance of the emergency generators when the emergency generators are not operational, including any delays thereto due to the inability to obtain parts or replacement equipment, Landlord shall have no obligation to provide Tenant with an alternative back-up generator or generators or alternative sources of back-up power. Tenant expressly acknowledges and agrees that Landlord does not guaranty that such emergency generators will be operational at all times or that emergency power will be available to the Premises when needed.

(d) **Energy Usage Data.** With respect to separately metered Utilities provided to the Premises that are paid for by Tenant directly to the Utility provider, if any, Tenant agrees to provide Landlord with access to Tenant's water and energy usage data on a monthly basis, by providing Tenant's applicable utility login credentials to Landlord's designated online portal. The costs and expenses incurred by Landlord in connection with receiving and analyzing such water and energy usage data (including, without limitation, as may be required pursuant to applicable Legal Requirements) shall be included as part of Operating Expenses.

## 12. Alterations and Tenant's Property.

(a) Any alterations, additions, or improvements made to the Premises by or on behalf of Tenant, including additional locks or bolts of any kind or nature upon any doors or windows in the Premises, but excluding installation, removal or realignment of furniture systems (other than removal of furniture systems owned or paid for by Landlord) not involving any modifications to the structure or connections (other than by ordinary plugs or jacks) to Building Systems (as defined in Section 13) ("**Alterations**") shall be subject to Landlord's prior written consent, which may be given or withheld in Landlord's sole discretion if any such Alteration affects the Building structure or Building Systems and shall not be otherwise unreasonably withheld, conditioned or delayed. Tenant may, subject to this terms of this Section 12, construct nonstructural Alterations in the Premises without Landlord's prior approval if the aggregate cost of all such work in any 12 month period does not exceed \$50,000.00 (a "**Notice-Only Alteration**"), provided Tenant notifies Landlord in writing of such intended Notice-Only Alteration, and such notice shall be



accompanied by plans, specifications, work contracts and such other information concerning the nature and cost of the Notice-Only Alteration as may be reasonably requested by Landlord, which notice and accompanying materials shall be delivered to Landlord not less than 15 business days in advance of any proposed construction. If Landlord approves any Alterations, Landlord may impose such conditions on Tenant in connection with the commencement, performance and completion of Alterations, including Notice-Only Alterations, as Landlord may deem appropriate in Landlord's reasonable discretion. Any request for approval of an Alteration shall be in writing, delivered not less than 15 business days in advance of any proposed construction, and accompanied by plans, specifications, bid proposals, work contracts and such other information concerning the nature and cost of the alterations as may be reasonably requested by Landlord, including the identities and mailing addresses of all persons performing work or supplying materials. Landlord's right to review plans and specifications and to monitor construction shall be solely for its own benefit, and Landlord shall have no duty to ensure that such plans and specifications or construction comply with applicable Legal Requirements. Tenant shall cause, at its sole cost and expense, all Alterations to comply with applicable insurance requirements and applicable Legal Requirements, and shall, subject to Section 7, implement at its sole cost and expense any alteration or modification required by Legal Requirements as a result of any Alterations. Other than in connection with Notice-Only Alterations, Tenant shall pay to Landlord, as Additional Rent, on demand an amount equal to 3% of all hard costs incurred by Tenant or its contractors or agents in connection with any Alteration to cover Landlord's overhead and expenses for plan review, coordination, scheduling and supervision. Before Tenant begins any Alteration, Landlord may post on and about the Premises notices of non-responsibility pursuant to applicable law. Tenant shall reimburse Landlord for, and indemnify and hold Landlord harmless from, any expense incurred by Landlord by reason of faulty work done by Tenant or its contractors, delays caused by such work, or inadequate cleanup.

(b) Upon Landlord's written request, Tenant shall furnish security or make other arrangements satisfactory to Landlord to assure payment for the completion of all Alterations work free and clear of liens. With respect to all Alterations, Tenant shall provide (and cause each contractor or subcontractor to provide) certificates of insurance for workers' compensation and other coverage in amounts and from an insurance company satisfactory to Landlord protecting Landlord against liability for personal injury or property damage during construction. Upon completion of any Alterations, Tenant shall deliver to Landlord: (i) sworn statements setting forth the names of all contractors and subcontractors who did the work and final lien waivers from all such contractors and subcontractors; and (ii) "as built" plans for any such Alteration.

(c) Other than (i) the items, if any, listed on **Exhibit F** attached hereto, (ii) any items agreed by Landlord in writing to be included on **Exhibit F** in the future, and (iii) any trade fixtures, machinery, equipment and other personal property not paid for all or in part by Landlord that may be removed without material damage to the Premises, which damage shall be repaired (including capping or terminating utility hook-ups behind walls) by Tenant during the Term (collectively, "**Tenant's Property**"), all Alterations, all fixtures, and all partitions, hardware, built-in machinery, built-in casework and cabinets and other similar additions, equipment, property and improvements built into the Premises so as to become an integral part of the Premises, including, without limitation, fume hoods that penetrate the roof or plenum area, built-in cold rooms, built-in warm rooms, walk-in cold rooms, walk-in warm rooms, clean rooms, deionized water systems, glass washing equipment, autoclaves, chillers, built-in plumbing, electrical and mechanical equipment and systems, and any power generator and transfer switch (collectively, "**Installations**") shall be and shall remain the property of Landlord during the Term and following the expiration or earlier termination of the Term, shall not be removed by Tenant at any time during the Term and shall remain upon and be surrendered with the Premises as a part thereof in accordance with Section 28 upon the expiration or earlier termination of this Lease. Notwithstanding the foregoing, Landlord may, at the time its approval of any such Installation is requested, or at the time it receives notice of a Notice-Only Alteration, notify Tenant in writing that Landlord requires that Tenant remove such Installation upon the expiration or earlier termination of the Term, in which event Tenant shall remove such Installation in accordance with the immediately succeeding sentence. If Landlord so elects, Tenant shall remove such Installation upon the expiration or earlier termination of this Lease and restore any damage caused by or occasioned as a result of such removal, including, when removing any of Tenant's Property that was plumbed, wired or otherwise connected to any of the Building Systems, capping off all such connections behind the walls of the Premises

and repairing any holes. Any restoration period beyond the expiration or earlier termination of the Term shall constitute a hold over pursuant to [Section 8](#). If Landlord is requested by Tenant or any lender, lessor or other person or entity claiming an interest in any of Tenant's Property to waive any lien Landlord may have against any of Tenant's Property, and Landlord consents to such waiver, then Landlord shall be entitled to reimbursement from Tenant for its actual, reasonable out-of-pocket costs incurred in connection with the preparation and negotiation of each such waiver of lien.

**13. Landlord's Repairs.** Landlord, as part of Operating Expenses, shall maintain (a) all of the structural, exterior, parking and other Common Areas of the Project, including, without limitation, the roof (and roof membrane), and (b) all Building systems serving both the Premises and other portions of the Project including, without limitation, HVAC, plumbing, fire sprinklers, elevators ("**Building Systems**"), in good repair, reasonable wear and tear and uninsured losses and damages caused by Tenant, or by any of Tenant's assignees, sublessees, licensees, agents, servants, employees, invitees and contractors (or any of Tenant's assignees, sublessees and/or licensees respective agents, servants, employees, invitees and contractors) (collectively, "**Tenant Parties**") excluded. Losses and damages caused by Tenant or any Tenant Party shall be repaired by Landlord, to the extent not covered by insurance, at Tenant's sole cost and expense. Landlord reserves the right to stop Building Systems services when necessary (i) by reason of accident or emergency, or (ii) for planned repairs, alterations or improvements, which are, in the judgment of Landlord, desirable or necessary to be made, until such repairs, alterations or improvements shall have been completed. Landlord shall have no responsibility or liability for failure to supply Building Systems services during any such period of interruption; provided, however, that Landlord shall, except in case of emergency, make a commercially reasonable effort to give Tenant 5 business days' advance notice of any planned stoppage of Building Systems services for routine maintenance, repairs, alterations or improvements. Landlord shall use reasonable efforts to minimize interference with Tenant's operations in the Premises in connection with the stoppage of Building Systems pursuant to this [Section 13](#). Tenant shall, to the extent that Tenant has actual knowledge thereof, promptly give Landlord written notice of any repair required by Landlord pursuant to this paragraph, after which Landlord shall make a commercially reasonable effort to effect such repair. Landlord shall not be liable for any failure to make any repairs or to perform any maintenance unless such failure shall persist for an unreasonable time after Tenant's written notice of the need for such repairs or maintenance. Tenant waives its rights under any state or local law to terminate this Lease or to make such repairs at Landlord's expense and agrees that the parties' respective rights with respect to such matters shall be solely as set forth herein. Repairs required as the result of fire, earthquake, flood, vandalism, war, or similar cause of damage or destruction shall be controlled by [Section 18](#).

**14. Tenant's Repairs.** Subject to [Section 13](#) hereof, Tenant, at its expense, shall repair, replace and maintain in good condition all portions of the Premises, including, without limitation, entries, doors, ceilings, interior windows, interior walls, and the interior side of demising walls. Should Tenant fail to make any such repair or replacement or fail to maintain the Premises, Landlord shall give Tenant notice of such failure. If Tenant fails to commence cure of such failure within 10 business days of Landlord's notice, and thereafter diligently prosecute such cure to completion, Landlord may perform such work and shall be reimbursed by Tenant within 30 days after demand therefor; provided, however, that if such failure by Tenant creates or could create an emergency, Landlord may immediately commence cure of such failure and shall thereafter be entitled to recover the costs of such cure from Tenant. Subject to [Sections 17](#) and [18](#), Tenant shall bear the full uninsured cost of any repair or replacement to any part of the Project that results from damage caused by Tenant or any Tenant Party and any repair that benefits only the Premises.

**15. Mechanic's Liens.** Tenant shall fully discharge of record from title or from the public record, by bond or otherwise, any mechanic's lien filed against the Premises or against the Project for work claimed to have been done for, or materials claimed to have been furnished to, Tenant within 10 business days after Tenant receives notice of the filing thereof, at Tenant's sole cost and shall otherwise keep the Premises and the Project free from any liens arising out of work performed, materials furnished or obligations incurred by Tenant. Should Tenant fail to fully discharge of record any lien described herein, Landlord shall have the right, but not the obligation, to pay such claim or post a bond or otherwise provide security to eliminate the lien as a claim against title to the Project and the costs incurred by Landlord in

connection therewith shall be immediately due from Tenant as Additional Rent. If Tenant shall lease or finance the acquisition of office equipment, furnishings, or other personal property of a removable nature utilized by Tenant in the operation of Tenant's business, Tenant warrants that any Uniform Commercial Code Financing Statement filed as a matter of public record by any lessor or creditor of Tenant will upon its face or by exhibit thereto indicate that such Financing Statement is applicable only to removable personal property of Tenant located within the Premises. In no event shall the address of the Project be furnished on the statement without qualifying language as to applicability of the lien only to removable personal property, located in the suite number designated to the Premises in the Basic Lease Provisions.

**16. Indemnification.** Tenant hereby indemnifies and agrees to defend, save and hold Landlord, its officers, directors, employees, managers, members, partners, agents, sub-agents, constituent entities and lease signators (collectively, "**Landlord Indemnified Parties**") harmless from and against any and all demands, claims, liabilities, losses, costs, expenses, actions, causes of action, damages or judgments, and all reasonable expenses incurred in investigating or resisting the same (including, without limitation, reasonable attorneys' fees, charges and disbursements and costs of suit) (collectively, "**Claims**") for injury or death to persons or damage to property occurring within or about the Premises or the Project arising directly or indirectly out of the use or occupancy of the Premises or the Project by Tenant or any Tenant Parties (including, without limitation, any act, omission or neglect by Tenant or any Tenant's Parties in or about the Premises or at the Project) or a breach or default by Tenant in the performance of any of its obligations hereunder, unless caused solely by the willful misconduct or gross negligence of Landlord Indemnified Parties. Landlord shall not be liable to Tenant for, and Tenant assumes all risk of damage to, personal property (including, without limitation, loss of records kept within the Premises). Tenant further waives any and all Claims for injury to Tenant's business or loss of income relating to any such damage or destruction of personal property (including, without limitation, any loss of records). Landlord Indemnified Parties shall not be liable for any damages arising from any act, omission or neglect of any tenant in the Project or of any other third party or Tenant Parties.

The provisions of this Section 16 shall survive the expiration or earlier termination of the Lease.

**17. Insurance.** Landlord shall maintain all risk property and, if applicable, sprinkler damage insurance covering the full replacement cost of the Project. Landlord shall further procure and maintain commercial general liability insurance with a single loss limit of not less than \$2,000,000 for bodily injury and property damage with respect to the Project. Landlord may, but is not obligated to, maintain such other insurance and additional coverages as it may deem necessary. All such insurance shall be included as part of the Operating Expenses. The Project may be included in a blanket policy (in which case the cost of such insurance allocable to the Project will be determined by Landlord based upon the insurer's cost calculations). Tenant shall also reimburse Landlord for any increased premiums or additional insurance that Landlord reasonably deems necessary as a result of Tenant's use of the Premises.

Tenant, at its sole cost and expense, shall maintain during the Term: all risk property insurance with business interruption and extra expense coverage, covering the full replacement cost of all property and improvements installed or placed in the Premises by Tenant at Tenant's expense; workers' compensation insurance with no less than the minimum limits required by law; employer's liability insurance with employers liability limits of \$1,000,000 bodily injury by accident – each accident, \$1,000,000 bodily injury by disease – policy limit, and \$1,000,000 bodily injury by disease – each employee; and commercial general liability insurance, with a minimum limit of not less than \$3,000,000 per occurrence for bodily injury and property damage with respect to the Premises. The commercial general liability insurance maintained by Tenant shall include Alexandria Real Estate Equities, Inc., and Landlord, its officers, directors, employees, managers, members, partners, agents, sub-agents, constituent entities and lease signators (collectively, "**Landlord Insured Parties**"), as additional insureds; insure on an occurrence and not a claims-made basis; be issued by insurance companies which have a rating of not less than policyholder rating of A and financial category rating of at least Class X in "Best's Insurance Guide"; not contain a hostile fire exclusion; contain a contractual liability endorsement; and provide primary coverage to Landlord Insured Parties (any policy issued to Landlord Insured Parties providing duplicate or similar coverage shall be deemed excess over Tenant's policies, regardless of limits). Tenant shall (i) provide Landlord with 30 days

advance written notice of cancellation of such commercial general liability policy, and (ii) request Tenant's insurer to endeavor to provide 30 days advance written notice to Landlord of cancellation of such commercial general liability policy (or 10 days in the event of a cancellation due to non-payment of premium). Certificates of insurance showing the limits of coverage required hereunder and showing the Landlord Insured Parties and Additional Insured Parties (as defined below) as an additional insureds, shall be delivered to Landlord by Tenant (i) concurrent with Tenant's delivery to Landlord of a copy of this Lease executed by Tenant, and (ii) prior to each renewal of said insurance. Tenant's policy may be a "blanket policy" with an aggregate per location endorsement which specifically provides that the amount of insurance shall not be prejudiced by other losses covered by the policy. Tenant shall, prior to the expiration of such policies, furnish Landlord with renewal certificates.

Upon written request of Landlord, Tenant shall, in addition to the Landlord Insured Parties, include the following parties as additional insureds under Tenant's commercial general liability insurance (collectively, "**Additional Insured Parties**"): (i) any Holder of a Mortgage encumbering the Project or any portion thereof, (ii) the landlord under any lease wherein Landlord is tenant of the real property on which the Project is located, if the interest of Landlord is or shall become that of a tenant under a ground or other underlying lease rather than that of a fee owner, and/or (iii) any management company retained by Landlord to manage the Project.

The property insurance obtained by Landlord and Tenant shall include a waiver of subrogation by the insurers and all rights based upon an assignment from its insured, against Landlord or Tenant, and their respective officers, directors, employees, managers, agents, invitees and contractors ("**Related Parties**"), in connection with any loss or damage thereby insured against. Neither party nor its respective Related Parties shall be liable to the other for loss or damage caused by any risk insured against under property insurance required to be maintained hereunder, and each party waives any claims against the other party, and its respective Related Parties, for such loss or damage. The failure of a party to insure its property shall not void this waiver. Landlord and its respective Related Parties shall not be liable for, and Tenant hereby waives all claims against such parties for, business interruption and losses occasioned thereby sustained by Tenant or any person claiming through Tenant resulting from any accident or occurrence in or upon the Premises or the Project from any cause whatsoever. If the foregoing waivers shall contravene any law with respect to exculpatory agreements, the liability of Landlord or Tenant shall be deemed not released but shall be secondary to the other's insurer.

Landlord may require insurance policy limits to be raised to conform with requirements of any Holder of a Mortgage encumbering the Project or any portion thereof and/or to bring coverage limits to levels then being generally required of new tenants within the Project.

**18. Restoration.** If, at any time during the Term, the Project or the Premises are damaged or destroyed by a fire or other casualty, Landlord shall notify Tenant within 60 days after discovery of such damage as to the amount of time Landlord reasonably estimates it will take to restore the Project or the Premises, as applicable (the "**Restoration Period**"). If the Restoration Period is estimated to exceed 12 months (the "**Maximum Restoration Period**"), Landlord may, in such notice, elect to terminate this Lease as of the date that is 75 days after the date of discovery of such damage or destruction; provided, however, that notwithstanding Landlord's election to restore, Tenant may elect to terminate this Lease by written notice from Tenant to Landlord delivered within 10 business days of receipt of a notice from Landlord estimating a Restoration Period for the Premises longer than the Maximum Restoration Period. Unless either Landlord or Tenant so elects to terminate this Lease, Landlord shall, subject to receipt of sufficient insurance proceeds (with any deductible to be treated as a current Operating Expense), promptly restore the Premises (excluding the improvements installed by Tenant or by Landlord and paid for by Tenant), subject to delays arising from the collection of insurance proceeds, from Force Majeure events or as needed to obtain any license, clearance or other authorization of any kind required to enter into and restore the Premises issued by any Governmental Authority having jurisdiction over the use, storage, handling, treatment, generation, release, disposal, removal or remediation of Hazardous Materials (as defined in Section 30) in, on or about the Premises (collectively referred to herein as "**Hazardous Materials Clearances**"); provided, however, that if repair or restoration of the Premises is not substantially complete

as of the end of the Maximum Restoration Period or, if longer, the Restoration Period, Landlord may, in its sole and absolute discretion, elect not to proceed with such repair and restoration, or Tenant may by written notice from Tenant to Landlord delivered within 10 business days of the expiration of the Maximum Restoration Period or, if longer, the Restoration Period, elect to terminate this Lease, in which event Landlord shall be relieved of its obligation to make such repairs or restoration and this Lease shall terminate as of the date that is 75 days after the later of: (i) discovery of such damage or destruction, or (ii) the date all required Hazardous Materials Clearances are obtained, but Landlord shall retain any Rent paid and the right to any Rent payable by Tenant prior to such election by Landlord or Tenant.

Promptly following the date that Landlord makes the Premises available to Tenant for Tenant's repairs and/or restoration, Tenant shall, at Tenant's expense, promptly perform, subject to delays arising from the collection of insurance proceeds, from Force Majeure events or to obtain Hazardous Materials Clearances, all repairs or restoration (which restoration shall be performed as an Alteration in accordance with Section 12) not required to be done by Landlord and shall promptly re-enter the Premises and commence doing business in accordance with this Lease. Notwithstanding the foregoing, either Landlord or Tenant may terminate this Lease upon written notice to the other if the Premises are damaged during the last year of the Term and Landlord reasonably estimates that it will take more than 2 months to repair such damage; provided, however, that such notice is delivered within 10 business days after the date that Landlord provides Tenant with written notice of the estimated Restoration Period. Notwithstanding anything to the contrary contained herein, Landlord shall also have the right to terminate this Lease if insurance proceeds are not available for such restoration. Base Rent shall be abated from the date all required Hazardous Materials Clearances are obtained until the Premises are repaired and restored, in the proportion that the area of the Premises, if any, that is not usable by Tenant bears to the total area of the Premises, unless Landlord provides Tenant with other space during the period of repair that is suitable for the temporary conduct of Tenant's business. In the event that no Hazardous Materials Clearances are required to be obtained by Tenant with respect to the Premises, Base Rent shall be abated commencing on the date of discovery of the damage or destruction. Such abatement shall be the sole remedy of Tenant, and except as provided in this Section 18, Tenant waives any right to terminate this Lease by reason of damage or casualty loss.

The provisions of this Lease, including this Section 18, constitute an express agreement between Landlord and Tenant with respect to any and all damage to, or destruction of, all or any part of the Premises, or any other portion of the Project, and any statute or regulation that is now or may hereafter be in effect shall have no application to this Lease or any damage or destruction to all or any part of the Premises or any other portion of the Project, the parties hereto expressly agreeing that this Section 18 sets forth their entire understanding and agreement with respect to such matters.

**19. Condemnation.** If the whole or any material part of the Premises or the Project is taken for any public or quasi-public use under governmental law, ordinance, or regulation, or by right of eminent domain, or by private purchase in lieu thereof (a "**Taking**" or "**Taken**"), and the Taking would either prevent or materially interfere with Tenant's use of the Premises or materially interfere with or impair Landlord's ownership or operation of the Project, then upon written notice by Landlord or Tenant to the other this Lease shall terminate and Rent shall be apportioned as of such date. If part of the Premises shall be Taken, and this Lease is not terminated as provided above, Landlord shall promptly restore the Premises and the Project as nearly as is commercially reasonable under the circumstances to their condition prior to such partial Taking and the rentable square footage of the Building, the rentable square footage of the Premises, Tenant's Share of Operating Expenses and the Rent payable hereunder during the unexpired Term shall be reduced to such extent as may be fair and reasonable under the circumstances. Upon any such Taking, Landlord shall be entitled to receive the entire price or award from any such Taking without any payment to Tenant, and Tenant hereby assigns to Landlord Tenant's interest, if any, in such award. Tenant shall have the right, to the extent that same shall not diminish Landlord's award, to make a separate claim against the condemning authority (but not Landlord) for such compensation as may be separately awarded or recoverable by Tenant for moving expenses and damage to Tenant's trade fixtures, if a separate award for such items is made to Tenant. Tenant hereby waives any and all rights it might otherwise have pursuant to any provision of state law to terminate this Lease upon a partial Taking of the Premises or the Project.



20. **Events of Default.** Each of the following events shall be a default (“**Default**”) by Tenant under this Lease:

(a) **Payment Defaults.** Tenant shall fail to pay any installment of Rent or any other payment hereunder when due; provided, however, that Landlord will give Tenant notice and an opportunity to cure any failure to pay Rent within 5 business days of any such notice not more than once in any 12 month period and Tenant agrees that such notice shall be in lieu of and not in addition to, or shall be deemed to be, any notice required by law.

(b) **Insurance.** Any insurance required to be maintained by Tenant pursuant to this Lease shall be canceled or terminated or shall expire or shall be reduced or materially changed, or Landlord shall receive a notice of nonrenewal of any such insurance and Tenant shall fail to obtain replacement insurance at least 5 days before the expiration of the current coverage.

(c) **Abandonment.** Tenant shall abandon the Premises. Tenant shall abandon the Premises for a period in excess of 180 days (for any reason other than a casualty, condemnation, a Force Majeure event or in connection with Alterations performed at the Premises). Tenant shall not be deemed to have abandoned the Premises if Tenant provides Landlord with reasonable advance notice prior to vacating and, at the time of vacating the Premises, (i) Tenant completes Tenant’s obligations under the Decommissioning and HazMat Closure Plan in compliance with Section 28, (ii) Tenant has obtained the release of the Premises of all Hazardous Materials Clearances and the Premises are free from any residual impact from the Tenant HazMat Operations and provides reasonably detailed documentation to Landlord confirming such matters, (iii) Tenant has made reasonable arrangements with Landlord for the security of the Premises for the balance of the Term, and (iv) Tenant continues during the balance of the Term to satisfy and perform all of Tenant’s obligations under this Lease as they come due.

(d) **Improper Transfer.** Tenant shall assign, sublease or otherwise transfer or attempt to transfer all or any portion of Tenant’s interest in this Lease or the Premises except as expressly permitted herein, or Tenant’s interest in this Lease shall be attached, executed upon, or otherwise judicially seized and such action is not released within 90 days of the action.

(e) **Liens.** Tenant shall fail to fully discharge or record or otherwise obtain the release of any lien placed upon the Premises in violation of this Lease within 10 business days after any such lien is filed against the Premises.

(f) **Insolvency Events.** Tenant or any guarantor or surety of Tenant’s obligations hereunder shall: (A) make a general assignment for the benefit of creditors; (B) commence any case, proceeding or other action seeking to have an order for relief entered on its behalf as a debtor or to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, liquidation, dissolution or composition of it or its debts or seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or of any substantial part of its property (collectively a “**Proceeding for Relief**”); (C) become the subject of any Proceeding for Relief that is not dismissed within 90 days of its filing or entry; or (D) die or suffer a legal disability (if Tenant, guarantor, or surety is an individual) or be dissolved or otherwise fail to maintain its legal existence (if Tenant, guarantor or surety is a corporation, partnership or other entity).

(g) **Estoppel Certificate or Subordination Agreement.** Tenant fails to execute any document required from Tenant under Sections 23 or 27 within 5 days after a second notice requesting such document.

(h) **Financial Information.** Tenant fails to provide any financial information required to be delivered by Tenant to Landlord pursuant to Section 42(c) following written request from Landlord, within 5 days after a second written notice requesting such financial information.

(i) **Security Deposit.** Tenant fails to comply with the requirements of Section 6.

(j) **Other Defaults.** Tenant shall fail to comply with any provision of this Lease other than those specifically referred to in this Section 20, and, except as otherwise expressly provided herein, such failure shall continue for a period of 30 days after written notice thereof from Landlord to Tenant. Any notice given under Section 20(j) hereof shall: (i) specify the alleged default, (ii) demand that Tenant cure such default, (iii) be in lieu of, and not in addition to, or shall be deemed to be, any notice required under any provision of applicable law, and (iv) not be deemed a forfeiture or a termination of this Lease unless Landlord elects otherwise in such notice. Notwithstanding the foregoing, if the nature of Tenant's default pursuant to Section 20(j) is such that it cannot be cured by the payment of funds, does not affect the safety, security or integrity of the Building or Building Systems or affect other occupants of the Project and reasonably requires more than 30 days to cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said 30 day period and thereafter diligently prosecutes the same to completion; provided, however, that such cure shall be completed no later than 45 days from the date of Landlord's notice.

## 21. Landlord's Remedies.

(a) **Payment By Landlord; Interest.** Upon a Default by Tenant hereunder, Landlord may, without waiving or releasing any obligation of Tenant hereunder, make such payment or perform such act. All sums so paid or incurred by Landlord, together with interest thereon, from the date such sums were paid or incurred, at the annual rate equal to 12% per annum or the highest rate permitted by law (the "**Default Rate**"), whichever is less, shall be payable to Landlord on demand as Additional Rent. Nothing herein shall be construed to create or impose a duty on Landlord to mitigate any damages resulting from Tenant's Default hereunder.

(b) **Late Payment Rent.** Late payment by Tenant to Landlord of Rent and other sums due will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges that may be imposed on Landlord under any Mortgage covering the Premises. Therefore, if any installment of Rent due from Tenant is not received by Landlord within 5 days after the date such payment is due, Tenant shall pay to Landlord an additional sum equal to 6% of the overdue Rent as a late charge. Notwithstanding the foregoing, before assessing a late charge the first time in any calendar year, Landlord shall provide Tenant written notice of the delinquency and will waive the right if Tenant pays such delinquency within 5 days thereafter. The parties agree that this late charge represents a fair and reasonable estimate of the costs Landlord will incur by reason of late payment by Tenant. In addition to the late charge, Rent not paid when due shall bear interest at the Default Rate from the 5th day after the date due until paid.

(c) **Remedies.** Upon the occurrence of a Default, Landlord, at its option, without further notice or demand to Tenant, shall have in addition to all other rights and remedies provided in this Lease, at law or in equity, the option to pursue any one or more of the following remedies, each and all of which shall be cumulative and nonexclusive, without any notice or demand whatsoever.

(i) Terminate this Lease, or at Landlord's option, Tenant's right to possession only, in which event Tenant shall immediately surrender the Premises to Landlord, and if Tenant fails to do so, Landlord may, without prejudice to any other remedy that it may have for possession or arrearages in rent, enter upon and take possession of the Premises and expel or remove Tenant and any other person who may be occupying the Premises or any part thereof, without being liable for prosecution or any claim or damages therefor;

(ii) Upon any termination of this Lease, whether pursuant to the foregoing Section 21(c)(i) or otherwise, Landlord may recover from Tenant the following:

(A) The worth at the time of award of any unpaid rent that has been earned at the time of such termination; plus

(B) The worth at the time of award of the amount by which the unpaid rent which would have been earned after termination until the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(C) The worth at the time of award of the amount by which the unpaid rent for the balance of the Term after the time of award exceeds the amount of such rental loss that Tenant proves could have been reasonably avoided; plus

(D) Any other amount necessary to compensate Landlord for all the detriment proximately caused by Tenant's failure to perform its obligations under this Lease or that in the ordinary course of things would be likely to result therefrom, specifically including, but not limited to, brokerage commissions and advertising expenses incurred, expenses of remodeling the Premises or any portion thereof for a new tenant, whether for the same or a different use, and any special concessions made to obtain a new tenant; and

(E) At Landlord's election, such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.

The term "rent" as used in this Section 21 shall be deemed to be and to mean all sums of every nature required to be paid by Tenant pursuant to the terms of this Lease, whether to Landlord or to others. As used in Sections 21(c)(ii)(A) and (B), above, the "worth at the time of award" shall be computed by allowing interest at the Default Rate. As used in Section 21(c)(ii)(C), above, the "worth at the time of award" shall be computed by discounting such amount at the discount rate of the Federal Reserve Bank of San Francisco at the time of award plus 1%.

(iii) Landlord may continue this Lease in effect after Tenant's Default and recover rent as it becomes due (Landlord and Tenant hereby agreeing that Tenant has the right to sublet or assign hereunder, subject only to the terms of Section 22). Accordingly, if Landlord does not elect to terminate this Lease following a Default by Tenant, Landlord may, from time to time, without terminating this Lease, enforce all of its rights and remedies hereunder, including the right to recover all Rent as it becomes due.

(iv) Whether or not Landlord elects to terminate this Lease following a Default by Tenant, Landlord shall have the right to terminate any and all subleases, licenses, concessions or other consensual arrangements for possession entered into by Tenant and affecting the Premises or may, in Landlord's sole discretion, succeed to Tenant's interest in such subleases, licenses, concessions or arrangements. Upon Landlord's election to succeed to Tenant's interest in any such subleases, licenses, concessions or arrangements, Tenant shall, as of the date of notice by Landlord of such election, have no further right to or interest in the rent or other consideration receivable thereunder.

(v) Independent of the exercise of any other remedy of Landlord hereunder or under applicable law, Landlord may conduct an environmental test of the Premises as generally described in Section 30(d) hereof, at Tenant's expense.

(d) **Effect of Exercise.** Exercise by Landlord of any remedies hereunder or otherwise available shall not be deemed to be an acceptance of surrender of the Premises and/or a termination of this Lease by Landlord, it being understood that such surrender and/or termination can be effected only by the express written agreement of Landlord and Tenant. Any law, usage, or custom to the contrary notwithstanding, Landlord shall have the right at all times to enforce the provisions of this Lease in strict accordance with the terms hereof; and the failure of Landlord at any time to enforce its rights under this Lease strictly in accordance with same shall not be construed as having created a custom in any way or manner contrary to the specific terms, provisions, and covenants of this Lease or as having modified the same and shall not be deemed a waiver of Landlord's right to enforce one or more of its rights in connection with any subsequent default. A receipt by Landlord of Rent or other payment with knowledge of the breach



of any covenant hereof shall not be deemed a waiver of such breach, and no waiver by Landlord of any provision of this Lease shall be deemed to have been made unless expressed in writing and signed by Landlord. To the greatest extent permitted by law, Tenant waives the service of notice of Landlord's intention to re-enter, re-take or otherwise obtain possession of the Premises as provided in any statute, or to institute legal proceedings to that end, and also waives all right of redemption in case Tenant shall be dispossessed by a judgment or by warrant of any court or judge. Any reletting of the Premises or any portion thereof shall be on such terms and conditions as Landlord in its sole discretion may determine. Landlord shall not be liable for, nor shall Tenant's obligations hereunder be diminished because of, Landlord's failure to relet the Premises or collect rent due in respect of such reletting or otherwise to mitigate any damages arising by reason of Tenant's Default.

## 22. Assignment and Subletting.

(a) **General Prohibition.** Without Landlord's prior written consent subject to and on the conditions described in this Section 22, Tenant shall not, directly or indirectly, voluntarily or by operation of law, assign this Lease or sublease the Premises or any part thereof or mortgage, pledge, or hypothecate its leasehold interest or grant any concession or license within the Premises, and any attempt to do any of the foregoing shall be void and of no effect. If Tenant is a corporation, partnership or limited liability company, the shares or other ownership interests thereof that are not actively traded upon a stock exchange or in the over-the-counter market, a transfer or series of transfers whereby 50% or more of the issued and outstanding shares or other ownership interests of such corporation are, or voting control is, transferred (but excepting transfers upon deaths of individual owners) from a person or persons or entity or entities that were owners thereof as of the Effective Date to persons or entities who were not owners of shares or other ownership interests of the corporation, partnership or limited liability company as of the Effective Date, shall be deemed an assignment of this Lease requiring the consent of Landlord as provided in this Section 22. Notwithstanding the foregoing, Tenant shall have the right to undergo a public offering which results in a change in control of Tenant and such change of control shall not constitute an assignment under this Section 22 requiring Landlord consent.

(b) **Permitted Transfers.** If Tenant desires to assign, sublease, hypothecate or otherwise transfer this Lease or sublet the Premises other than pursuant to a Permitted Assignment (as defined below), then at least 15 business days, but not more than 90 calendar days, before the date Tenant desires the assignment or sublease to be effective (the "**Assignment Date**"), Tenant shall give Landlord a notice (the "**Assignment Notice**") containing such information about the proposed assignee or sublessee, including the proposed use of the Premises and any Hazardous Materials proposed to be used, stored handled, treated, generated in or released or disposed of from the Premises, the Assignment Date, any relationship between Tenant and the proposed assignee or sublessee, and all material terms and conditions of the proposed assignment or sublease, including a copy of any proposed assignment or sublease in its final form, and such other information as Landlord may deem reasonably necessary or appropriate to its consideration whether to grant its consent. Landlord may, by giving written notice to Tenant within 15 business days after receipt of the Assignment Notice: (i) grant such consent (provided that Landlord shall further have the right to review and approve or disapprove the proposed form of sublease prior to the effective date of any such subletting), or (ii) refuse such consent, in its reasonable discretion. Among other reasons, it shall be reasonable for Landlord to withhold its consent in any of these instances: (1) the proposed assignee or subtenant is a governmental agency; (2) in Landlord's reasonable judgment, the use of the Premises by the proposed assignee or subtenant would entail any alterations that would lessen the value of the leasehold improvements in the Premises, or would require increased services by Landlord; (3) in Landlord's reasonable judgment, the proposed assignee or subtenant is engaged in areas of scientific research or other business concerns that are controversial; (4) in Landlord's reasonable judgment, the proposed assignee or subtenant lacks the creditworthiness to support the financial obligations it will incur under the proposed assignment or sublease; (5) in Landlord's reasonable judgment, the character, reputation, or business of the proposed assignee or subtenant is inconsistent with the desired tenant-mix or the quality of other tenancies in the Project or is inconsistent with the type and quality of the nature of the Building; (6) intentionally omitted; (7) Landlord or an affiliate of Landlord has experienced previous defaults by or is in litigation with the proposed assignee or subtenant; (8) the use of the Premises by the

proposed assignee or subtenant will violate any applicable Legal Requirement; (9) intentionally omitted; (10) the proposed assignee or subtenant is an entity with whom Landlord is then currently negotiating to lease space in the Project and Landlord has comparable space available to lease; or (11) the assignment or sublease is prohibited by the Holder of a Mortgage encumbering all or a portion of the Project. No failure of Landlord to deliver a timely notice in response to the Assignment Notice shall be deemed to be Landlord's consent to the proposed assignment, sublease or other transfer. Tenant shall pay to Landlord a fee equal to Two Thousand Five Hundred Dollars (\$2,500) in connection with its consideration of any Assignment Notice and/or its preparation or review of any consent documents. Notwithstanding the foregoing, Landlord's consent to an assignment of this Lease or a subletting of any portion of the Premises to any entity controlling, controlled by or under common control with Tenant (a "**Control Permitted Assignment**") shall not be required, provided that Tenant and any assignee or sublessee shall execute a reasonable form of acknowledgment of assignment or sublease, as applicable, acceptable to Landlord on or before the effective date of the Control Permitted Assignment.

In addition, Tenant shall have the right to assign this Lease, upon 30 days prior written notice to Landlord ((x) unless Tenant is prohibited from providing such notice by applicable Legal Requirements in which case Tenant shall notify Landlord promptly thereafter, and (y) if the transaction is subject to confidentiality requirements, Tenant's advance notification shall be subject to Landlord's execution of a non-disclosure agreement reasonably acceptable to Landlord and Tenant) but without obtaining Landlord's prior written consent, to a corporation or other entity which is a successor-in-interest to Tenant, by way of merger, consolidation or corporate reorganization, or by the purchase of all or substantially all of the assets or the ownership interests of Tenant provided that (i) such merger or consolidation, or such acquisition or assumption, as the case may be, is for a good business purpose and not principally for the purpose of transferring this Lease, and (ii) the net worth (as determined in accordance with generally accepted accounting principles ("**GAAP**") of the assignee is not less than the greater of the net worth (as determined in accordance with GAAP) of Tenant as of (A) the Commencement Date, or (B) as of the date of Tenant's most current quarterly or annual financial statements, and (iii) within 5 days after the effective date of the Corporate Permitted Assignment, Tenant and such assignee shall execute a reasonable form of acknowledgment of assignment reasonably acceptable to Landlord pursuant to which, among other things, such assignee shall agree in writing to assume all of the terms, covenants and conditions of this Lease, and the assignee shall deliver a certificate of insurance to Landlord satisfying the Tenant's insurance requirements under Section 17 (a "**Corporate Permitted Assignment**"). Control Permitted Assignments and Corporate Permitted Assignments are hereinafter referred to as "**Permitted Assignments**."

(c) **Additional Conditions.** As a condition to any such assignment or subletting, whether or not Landlord's consent is required, Landlord may require:

(i) that any assignee or subtenant agree, in writing at the time of such assignment or subletting, that if Landlord gives such party notice that Tenant is in default under this Lease, such party shall thereafter make all payments otherwise due Tenant directly to Landlord, which payments will be received by Landlord without any liability except to credit such payment against those due under this Lease, and any such third party shall agree to attorn to Landlord or its successors and assigns should this Lease be terminated for any reason; provided, however, in no event shall Landlord or its successors or assigns be obligated to accept such attornment; and

(ii) A list of Hazardous Materials, certified by the proposed assignee or sublessee to be true and correct, which the proposed assignee or sublessee intends to use, store, handle, treat, generate in or release or dispose of from the Premises, together with copies of all documents relating to such use, storage, handling, treatment, generation, release or disposal of Hazardous Materials by the proposed assignee or subtenant in the Premises or on the Project, prior to the proposed assignment or subletting, including, without limitation: permits; approvals; reports and correspondence; storage and management plans; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given its written consent to do so, which consent may be withheld in Landlord's sole and absolute discretion); and all closure plans or any other documents required by

any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks. Neither Tenant nor any such proposed assignee or subtenant is required, however, to provide Landlord with any portion(s) of the such documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities.

(d) **No Release of Tenant, Sharing of Excess Rents.** Notwithstanding any assignment or subletting, Tenant and any guarantor or surety of Tenant's obligations under this Lease shall at all times remain fully and primarily responsible and liable for the payment of Rent and for compliance with all of Tenant's other obligations under this Lease. If the rent due and payable by a sublessee or assignee (or a combination of the rental payable under such sublease or assignment plus any bonus or other consideration attributable to Tenant's interest in this Lease or incident thereto in any form) exceeds the sum of the Base Rent and Operating Expenses payable under this Lease (or, during the Subsequent Abatement Period, Base Rent that would have been payable during the Subsequent Abatement Period but for the abatement of Base Rent provided for in Section 3(a)) with respect to the applicable portion of the Premises (excluding however, any Rent payable under this Section) and actual and reasonable and customary brokerage fees, legal costs, market inducements, improvement allowances, and any design or construction fees (collectively, the "**Sublease/Assignment Costs**") directly related to and required pursuant to the terms of any such sublease or assignment ("**Excess Rents**"), then Tenant shall be bound and obligated to pay Landlord as Additional Rent hereunder 50% of such Excess Rent within 30 days following receipt thereof by Tenant. For the purpose of calculating Excess Rents, the Sublease/Assignment Costs shall be amortized on a straight-lined basis over the term of the applicable sublease or assignment. If Tenant shall sublet the Premises or any part thereof, Tenant hereby immediately and irrevocably assigns to Landlord, as security for Tenant's obligations under this Lease, all rent from any such subletting, and Landlord or a receiver for Tenant appointed on Landlord's application, may collect such rent and apply it toward Tenant's obligations under this Lease; except that, until the occurrence of a Default, Tenant shall have the right to collect such rent.

(e) **No Waiver.** The consent by Landlord to an assignment or subletting shall not relieve Tenant or any assignees of this Lease or any sublessees of the Premises from obtaining the consent of Landlord to any further assignment or subletting nor shall it release Tenant or any assignee or sublessee of Tenant from full and primary liability under this Lease. The acceptance of Rent hereunder, or the acceptance of performance of any other term, covenant, or condition thereof, from any other person or entity shall not be deemed to be a waiver of any of the provisions of this Lease or a consent to any subletting, assignment or other transfer of the Premises.

(f) **Prior Conduct of Proposed Transferee.** Notwithstanding any other provision of this Section 22, if (i) the proposed assignee or sublessee of Tenant has been required by any prior landlord, lender or Governmental Authority to take remedial action in connection with Hazardous Materials contaminating a property, where the contamination resulted from such party's action or use of the property in question, (ii) the proposed assignee or sublessee is subject to an enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority), or (iii) because of the existence of a pre-existing environmental condition in the vicinity of or underlying the Project, the risk that Landlord would be targeted as a responsible party in connection with the remediation of such pre-existing environmental condition would be materially increased or exacerbated by the proposed use of Hazardous Materials by such proposed assignee or sublessee, Landlord shall have the absolute right to refuse to consent to any assignment or subletting to any such party.

**23. Estoppel Certificate.** Tenant shall, within 10 business days of written notice from Landlord, execute, acknowledge and deliver a statement in writing in any form reasonably requested by a proposed lender or purchaser, (i) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified is in full force and effect) and the dates to which the rental and other charges are paid in advance, if any, (ii)

acknowledging that there are not any uncured defaults on the part of Landlord hereunder, or specifying such defaults if any are claimed, and (iii) setting forth such further information with respect to the status of this Lease or the Premises as may be reasonably requested thereon. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Premises are a part. Tenant's failure to deliver such statement within 5 days after Tenant's receipt of a second written notice from Landlord shall be conclusive upon Tenant that this Lease is in full force and effect and without modification except as may be represented by Landlord in any certificate prepared by Landlord and delivered to Tenant for execution.

**24. Quiet Enjoyment.** So long as Tenant is not in Default under this Lease, Tenant shall, subject to the terms of this Lease, at all times during the Term, have peaceful and quiet enjoyment of the Premises against any person claiming by, through or under Landlord.

**25. Prorations.** All prorations required or permitted to be made hereunder shall be made on the basis of a 360 day year and 30 day months.

**26. Rules and Regulations.** Tenant shall, at all times during the Term and any extension thereof, comply with all reasonable rules and regulations at any time or from time to time established by Landlord covering use of the Premises and the Project. Such rules and regulations may include, without limitation, rules and regulations relating to the use of the Project Amenities and/or rules and regulations which are intended to encourage social distancing, promote and protect health and physical well-being within the Building and the Project and/or intended to limit the spread of communicable diseases and/or viruses of any kind or nature that are more virulent than the seasonal flu (collectively, "**Infectious Conditions**"), provided that such rules and regulations are in compliance with applicable Legal Requirements and applied to all tenants of the Project on a non-discriminatory basis. The current rules and regulations are attached hereto as **Exhibit E**. If there is any conflict between such rules and regulations and other provisions of this Lease, the terms and provisions of this Lease shall control. Landlord shall not have any liability or obligation for the breach of any rules or regulations by other tenants in the Project and shall not enforce such rules and regulations in a discriminatory manner.

**27. Subordination.** This Lease and Tenant's interest and rights hereunder are hereby made and shall be subject and subordinate at all times to the lien of any Mortgage now existing or hereafter created on or against the Project or the Premises, and all amendments, restatements, renewals, modifications, consolidations, refinancing, assignments and extensions thereof, without the necessity of any further instrument or act on the part of Tenant; provided, however that so long as there is no Default hereunder, Tenant's right to possession of the Premises shall not be disturbed by the Holder of any such Mortgage. Tenant agrees, at the election of the Holder of any such Mortgage, to attorn to any such Holder. Tenant agrees upon demand to execute, acknowledge and deliver such instruments, confirming such subordination, and such instruments of attornment as shall be requested by any such Holder, provided any such instruments contain appropriate non-disturbance provisions assuring Tenant's quiet enjoyment of the Premises as set forth in Section 24 hereof. Notwithstanding the foregoing, any such Holder may at any time subordinate its Mortgage to this Lease, without Tenant's consent, by notice in writing to Tenant, and thereupon this Lease shall be deemed prior to such Mortgage without regard to their respective dates of execution, delivery or recording and in that event such Holder shall have the same rights with respect to this Lease as though this Lease had been executed prior to the execution, delivery and recording of such Mortgage and had been assigned to such Holder. The term "**Mortgage**" whenever used in this Lease shall be deemed to include deeds of trust, security assignments and any other encumbrances, and any reference to the "**Holder**" of a Mortgage shall be deemed to include the beneficiary under a deed of trust.

As of the Effective Date, there is no existing Mortgage encumbering the Project.

**28. Surrender.** Upon the expiration of the Term or earlier termination of Tenant's right of possession, Tenant shall surrender the Premises to Landlord in broom clean condition (a) in the same condition as received (except for any Alterations or Installations permitted by Landlord to remain in the Premises pursuant to Section 12), subject to ordinary wear and tear and casualty loss and condemnation

covered by Sections 18 and 19, (b) with all wires, cables or similar equipment which Tenant has installed in the Premises or in the risers or plenums of the Building removed, (c) free of Hazardous Materials brought upon, kept, used, stored, handled, treated, generated in, or released or disposed of from, the Premises by any person other than Landlord or any of Landlord's employees, agents and contractors (collectively, "Tenant HazMat Operations"), and (d) released of all Hazardous Materials Clearances. At least 3 months prior to the surrender of the Premises or such earlier date as Tenant may elect to cease operations at the Premises, Tenant shall deliver to Landlord a narrative description of the actions proposed (or required by any Governmental Authority) to be taken by Tenant in order to surrender the Premises (including any Installations permitted by Landlord to remain in the Premises) at the expiration or earlier termination of the Term, free from any residual impact from the Tenant HazMat Operations and otherwise released for unrestricted use and occupancy (the "Decommissioning and HazMat Closure Plan"). Such Decommissioning and HazMat Closure Plan shall be accompanied by a current listing of (i) all Hazardous Materials licenses and permits held by or on behalf of any Tenant Party with respect to the Premises, and (ii) all Hazardous Materials used, stored, handled, treated, generated, released or disposed of from the Premises, and shall be subject to the review and approval of Landlord's environmental consultant. In connection with the review and approval of the Decommissioning and HazMat Closure Plan, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning Tenant HazMat Operations as Landlord shall request. On or before such surrender, Tenant shall deliver to Landlord evidence that the approved Decommissioning and HazMat Closure Plan shall have been satisfactorily completed and Landlord shall have the right to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the effective date of such surrender or early termination of this Lease, free from any residual impact from Tenant HazMat Operations. Tenant shall reimburse Landlord for its actual, out-of-pocket costs incurred in connection with its review of the Decommissioning and HazMat Closure Plan and Tenant's implementation of the same by Landlord's environmental consultant; provided such amount shall not exceed \$5,000. Landlord shall have the unrestricted right to deliver such Decommissioning and HazMat Closure Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties.

If Tenant shall fail to prepare or submit a Decommissioning and HazMat Closure Plan approved by Landlord, or if Tenant shall fail to complete the approved Decommissioning and HazMat Closure Plan, or if such Decommissioning and HazMat Closure Plan, whether or not approved by Landlord, shall fail to adequately address any residual effect of Tenant HazMat Operations in, on or about the Premises, Landlord shall have the right to take such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Project are surrendered free from any residual impact from Tenant HazMat Operations, the cost of which actions shall be reimbursed by Tenant as Additional Rent, without regard to the limitation set forth in the first paragraph of this Section 28.

Upon the expiration or earlier termination of the Term, Tenant shall immediately return to Landlord all keys and/or access cards to parking, the Project, restrooms or all or any portion of the Premises furnished to or otherwise procured by Tenant. If any such access card or key is lost, Tenant shall pay to Landlord, at Landlord's election, either the cost of replacing such lost access card or key or the cost of reprogramming the access security system in which such access card was used or changing the lock or locks opened by such lost key. Any Tenant's Property, Alterations and property not so removed by Tenant as permitted or required herein shall be deemed abandoned and may be stored, removed, and disposed of by Landlord at Tenant's expense, and Tenant waives all claims against Landlord for any damages resulting from Landlord's retention and/or disposition of such property. All obligations of Tenant hereunder not fully performed as of the termination of the Term, including the obligations of Tenant under Section 30 hereof, shall survive the expiration or earlier termination of the Term, including, without limitation, indemnity obligations, payment obligations with respect to Rent and obligations concerning the condition and repair of the Premises.

**29. Waiver of Jury Trial.** TO THE EXTENT PERMITTED BY LAW, TENANT AND LANDLORD WAIVE ANY RIGHT TO TRIAL BY JURY OR TO HAVE A JURY PARTICIPATE IN RESOLVING ANY DISPUTE, WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE,

BETWEEN LANDLORD AND TENANT ARISING OUT OF THIS LEASE OR ANY OTHER INSTRUMENT, DOCUMENT, OR AGREEMENT EXECUTED OR DELIVERED IN CONNECTION HERewith OR THE TRANSACTIONS RELATED HERETO.

### 30. Environmental Requirements.

(a) **Prohibition/Compliance/Indemnity.** Tenant shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises or the Project in violation of applicable Environmental Requirements (as hereinafter defined) by Tenant or any Tenant Party. Nothing herein shall prohibit Tenant from keeping, using and storing in the Premises Hazardous Materials contained in products customarily used by tenants in de minimis quantities for ordinary cleaning and office purposes. If Tenant breaches the obligation stated in the preceding sentence, or if the presence of Hazardous Materials in the Premises during the Term or any holding over results in contamination of the Premises, the Project or any adjacent property or if contamination of the Premises, the Project or any adjacent property by Hazardous Materials brought into, kept, used, stored, handled, treated, generated in or about, or released or disposed of from, the Premises by anyone other than Landlord and Landlord's employees, agents and contractors otherwise occurs during the Term or any holding over, Tenant hereby indemnifies and shall defend and hold Landlord, its officers, directors, employees, agents and contractors harmless from any and all actions (including, without limitation, remedial or enforcement actions of any kind, administrative or judicial proceedings, and orders or judgments arising out of or resulting therefrom), costs, claims, damages (including, without limitation, punitive damages and damages based upon diminution in value of the Premises or the Project, or the loss of, or restriction on, use of the Premises or any portion of the Project), expenses (including, without limitation, attorneys', consultants' and experts' fees, court costs and amounts paid in settlement of any claims or actions), fines, forfeitures or other civil, administrative or criminal penalties, injunctive or other relief (whether or not based upon personal injury, property damage, or contamination of, or adverse effects upon, the environment, water tables or natural resources), liabilities or losses which arise during or after the Term as a result of such contamination. This indemnification of Landlord by Tenant includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, treatment, remedial, removal, or restoration work required by any federal, state or local Governmental Authority because of Hazardous Materials present in the air, soil or ground water above, on, or under the Premises. Without limiting the foregoing, if the presence of any Hazardous Materials on the Premises, the Project or any adjacent property caused or permitted by Tenant or any Tenant Party results in any contamination of the Premises, the Project or any adjacent property, Tenant shall promptly take all actions at its sole expense and in accordance with applicable Environmental Requirements as are necessary to return the Premises, the Project or any adjacent property to the condition existing prior to the time of such contamination, provided that Landlord's approval of such action shall first be obtained, which approval shall not unreasonably be withheld so long as such actions would not potentially have any material adverse long-term or short-term effect on the Premises or the Project. Notwithstanding anything to the contrary contained in this Section 30, Tenant shall not be responsible for, and the indemnification and hold harmless obligation set forth in this paragraph shall not apply to (i) contamination in the Premises which Tenant can prove to Landlord's reasonable satisfaction existed in the Premises immediately prior to the Commencement Date, or (ii) the presence of any Hazardous Materials in the Premises which Tenant can prove to Landlord's reasonable satisfaction migrated from outside of the Premises into the Premises, unless in either case, the presence of such Hazardous Materials (x) is the result of a breach by Tenant of any of its obligations under this Lease, or (y) was caused, contributed to or exacerbated by Tenant or any Tenant Party. The provisions of this Section 30 shall survive the expiration or earlier termination of this Lease.

(b) **Business.** Landlord acknowledges that it is not the intent of this Section 30 to prohibit Tenant from using the Premises for the Permitted Use. Tenant may operate its business according to prudent industry practices so long as the use or presence of Hazardous Materials is strictly and properly monitored according to all then applicable Environmental Requirements. As a material inducement to Landlord to allow Tenant to use Hazardous Materials in connection with its business, Tenant agrees to deliver to Landlord prior to the Commencement Date a list identifying each type of Hazardous Materials (other than products customarily used by tenants in de minimis quantities for ordinary cleaning and office

purposes) to be brought upon, kept, used, stored, handled, treated, generated on, or released or disposed of from, the Premises and setting forth any and all governmental approvals or permits required in connection with the presence, use, storage, handling, treatment, generation, release or disposal of such Hazardous Materials on or from the Premises (“**Hazardous Materials List**”). Upon Landlord’s request, or any time that Tenant is required to deliver a Hazardous Materials List to any Governmental Authority (e.g., the fire department) in connection with Tenant’s use or occupancy of the Premises, Tenant shall deliver to Landlord a copy of such Hazardous Materials List. Tenant shall deliver to Landlord true and correct copies of the following documents (the “**Haz Mat Documents**”) relating to the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials prior to the Commencement Date, or if unavailable at that time, concurrent with the receipt from or submission to a Governmental Authority: permits; approvals; reports and correspondence; storage and management plans, notice of violations of any Legal Requirements; plans relating to the installation of any storage tanks to be installed in or under the Project (provided, said installation of tanks shall only be permitted after Landlord has given Tenant its written consent to do so, which consent may be withheld in Landlord’s sole and absolute discretion); and all closure plans or any other documents required by any and all federal, state and local Governmental Authorities for any storage tanks installed in, on or under the Project for the closure of any such tanks. Tenant is not required, however, to provide Landlord with any portion(s) of the Haz Mat Documents containing information of a proprietary nature which, in and of themselves, do not contain a reference to any Hazardous Materials or hazardous activities. It is not the intent of this Section to provide Landlord with information which could be detrimental to Tenant’s business should such information become possessed by Tenant’s competitors.

(c) **Tenant Representation and Warranty.** Tenant hereby represents and warrants to Landlord that (i) neither Tenant nor any of its legal predecessors has been required by any prior landlord, lender or Governmental Authority at any time to take remedial action in connection with Hazardous Materials contaminating a property which contamination was permitted by Tenant or such predecessor or resulted from Tenant’s or such predecessor’s action or use of the property in question, and (ii) Tenant is not subject to any enforcement order issued by any Governmental Authority in connection with the use, storage, handling, treatment, generation, release or disposal of Hazardous Materials (including, without limitation, any order related to the failure to make a required reporting to any Governmental Authority). If Landlord determines that this representation and warranty was not true as of the Effective Date, Landlord shall have the right to terminate this Lease in Landlord’s sole and absolute discretion.

(d) **Testing.** Landlord shall have the right, but not the obligation, to conduct annual tests of the Premises to determine whether any contamination of the Premises or the Project has occurred as a result of Tenant’s use. Tenant shall be required to pay the cost of such annual test of the Premises if there is violation of this [Section 30](#) or if contamination for which Tenant is responsible under this [Section 30](#) is identified; provided, however, that if Tenant conducts its own tests of the Premises using third party contractors and test procedures acceptable to Landlord which tests are certified to Landlord, Landlord shall accept such tests in lieu of the annual tests to be paid for by Tenant. In addition, at any time, and from time to time, prior to the expiration or earlier termination of the Term, Landlord shall have the right to conduct appropriate tests of the Premises and the Project to determine if contamination has occurred as a result of Tenant’s use of the Premises. In connection with such testing, upon the request of Landlord, Tenant shall deliver to Landlord or its consultant such non-proprietary information concerning the use of Hazardous Materials in or about the Premises by Tenant or any Tenant Party. If contamination has occurred for which Tenant is liable under this [Section 30](#), Tenant shall pay all costs to conduct such tests. If no such contamination is found, Landlord shall pay the costs of such tests (which shall not constitute an Operating Expense). Landlord shall provide Tenant with a copy of all third party, non-confidential reports and tests of the Premises made by or on behalf of Landlord during the Term without representation or warranty and subject to a confidentiality agreement. Tenant shall, at its sole cost and expense, promptly and satisfactorily remediate any environmental conditions identified by such testing in accordance with all Environmental Requirements. Landlord’s receipt of or satisfaction with any environmental assessment in no way waives any rights that Landlord may have against Tenant. Subject to the terms of [Section 32](#) below, Tenant shall have the right to have a Tenant representative present while Landlord conducts tests in the Premises pursuant to this [Section 30\(d\)](#).



(e) **Control Areas.** Tenant shall be allowed to utilize up to its pro rata share of the Hazardous Materials inventory within any control area or zone (located within the Premises), as designated by the applicable building code, for chemical use or storage. As used in the preceding sentence, Tenant's pro rata share of any control areas or zones located within the Premises shall be determined based on the rentable square footage that Tenant leases within the applicable control area or zone. For purposes of example only, if a control area or zone contains 10,000 rentable square feet and 2,000 rentable square feet of a tenant's premises are located within such control area or zone (while such premises as a whole contains 5,000 rentable square feet), the applicable tenant's pro rata share of such control area would be 20%.

(f) **Storage Tanks.** If storage tanks storing Hazardous Materials located on the Premises or the Project are used by Tenant or are hereafter placed on the Premises or the Project by Tenant, Tenant shall install, use, monitor, operate, maintain, upgrade and manage such storage tanks, maintain appropriate records, obtain and maintain appropriate insurance, implement reporting procedures, properly close any storage tanks, and take or cause to be taken all other actions necessary or required under applicable state and federal Legal Requirements, as such now exists or may hereafter be adopted or amended in connection with the installation, use, maintenance, management, operation, upgrading and closure of such storage tanks. Notwithstanding anything to the contrary contained herein, Tenant shall have no right to use or install any underground storage tanks at the Project.

(g) **Tenant's Obligations.** Tenant's obligations under this Section 30 shall survive the expiration or earlier termination of the Lease. Any period after the expiration or earlier termination of this Lease required by Tenant or Landlord to complete the removal from the Premises of any Hazardous Materials (including, without limitation, the release and termination of any licenses or permits restricting the use of the Premises and the completion of the approved Decommissioning and HazMat Closure Plan) shall constitute a hold over pursuant to Section 8.

(h) **Definitions.** As used herein, the term "**Environmental Requirements**" means all applicable present and future statutes, regulations, ordinances, rules, codes, judgments, orders or other similar enactments of any Governmental Authority regulating or relating to health, safety, or environmental conditions on, under, or about the Premises or the Project, or the environment, including without limitation, the following: the Comprehensive Environmental Response, Compensation and Liability Act; the Resource Conservation and Recovery Act; and all state and local counterparts thereto, and any regulations or policies promulgated or issued thereunder. As used herein, the term "**Hazardous Materials**" means and includes any substance, material, waste, pollutant, or contaminant listed or defined as hazardous or toxic, or regulated by reason of its impact or potential impact on humans, animals and/or the environment under any Environmental Requirements, asbestos and petroleum, including crude oil or any fraction thereof, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). As defined in Environmental Requirements, Tenant is and shall be deemed to be the "**operator**" of Tenant's "**facility**" and the "**owner**" of all Hazardous Materials brought on the Premises by Tenant or any Tenant Party, and the wastes, by-products, or residues generated, resulting, or produced therefrom.

**31. Tenant's Remedies/Limitation of Liability.** Landlord shall not be in default hereunder unless Landlord fails to perform any of its obligations hereunder within 30 days after written notice from Tenant specifying such failure (unless such performance will, due to the nature of the obligation, require a period of time in excess of 30 days, then after such period of time as is reasonably necessary). Upon any default by Landlord, Tenant shall give notice by registered or certified mail to any Holder of a Mortgage covering the Premises and to any landlord of any lease of property in or on which the Premises are located and Tenant shall offer such Holder and/or landlord a reasonable opportunity to cure the default, including time to obtain possession of the Project by power of sale or a judicial action if such should prove necessary to effect a cure; provided Landlord shall have furnished to Tenant in writing the names and addresses of all such persons who are to receive such notices. All obligations of Landlord hereunder shall be construed as covenants, not conditions; and, except as may be otherwise expressly provided in this Lease, Tenant may not terminate this Lease for breach of Landlord's obligations hereunder.



Notwithstanding the foregoing, if any claimed Landlord default hereunder will immediately, materially and adversely affect Tenant's ability to conduct its business in the Premises (a "**Material Landlord Default**"), Tenant shall, as soon as reasonably possible, but in any event within 2 business days of obtaining knowledge of such claimed Material Landlord Default, give Landlord written notice of such claim which notice shall specifically state that a Material Landlord Default exists and telephonic notice to Tenant's principal contact with Landlord. Landlord shall then have 2 business days to commence cure of such claimed Material Landlord Default and shall diligently prosecute such cure to completion. If such claimed Material Landlord Default is not a default by Landlord hereunder, or if Tenant failed to give Landlord the notice required hereunder within 2 business days of learning of the conditions giving rise to the claimed Material Landlord Default, Landlord shall be entitled to recover from Tenant, as Additional Rent, any costs incurred by Landlord in connection with such cure in excess of the costs, if any, that Landlord would otherwise have been liable to pay hereunder. If Landlord fails to commence cure of any claimed Material Landlord Default as provided above, Tenant may commence and prosecute such cure to completion provided that it does not affect any Building Systems, the Building structure or the Common Areas or adversely impact other occupants of the Building, and shall be entitled to recover the costs of such cure (but not any consequential or other damages) from Landlord by way of reimbursement from Landlord with no right to offset against Rent, to the extent of Landlord's obligation to cure such claimed Material Landlord Default hereunder, subject to the limitations set forth in the immediately preceding sentence of this paragraph and the other provisions of this Lease.

Notwithstanding the foregoing, if any claimed Landlord default hereunder will immediately, materially and adversely affect Tenant's ability to conduct its business in the Premises (a "**Material Landlord Default**"), Tenant shall, as soon as reasonably possible, but in any event within 2 business days of obtaining knowledge of such claimed Material Landlord Default, give Landlord written notice of such claim which notice shall specifically state that a Material Landlord Default exists and telephonic notice to Tenant's principal contact with Landlord. Landlord shall then have 2 business days to commence cure of such claimed Material Landlord Default and shall diligently prosecute such cure to completion. If such claimed Material Landlord Default is not a default by Landlord hereunder, or if Tenant failed to give Landlord the notice required hereunder within 2 business days of learning of the conditions giving rise to the claimed Material Landlord Default, Landlord shall be entitled to recover from Tenant, as Additional Rent, any costs incurred by Landlord in connection with such cure in excess of the costs, if any, that Landlord would otherwise have been liable to pay hereunder. If Landlord fails to commence cure of any claimed Material Landlord Default as provided above, Tenant may commence and prosecute such cure to completion provided that it does not affect any Building Systems, the Building structure or the Common Areas or adversely impact other occupants of the Building, and shall be entitled to recover the costs of such cure (but not any consequential or other damages) from Landlord by way of reimbursement from Landlord with no right to offset against Rent, to the extent of Landlord's obligation to cure such claimed Material Landlord Default hereunder, subject to the limitations set forth in the immediately preceding sentence of this paragraph and the other provisions of this Lease.

All obligations of Landlord under this Lease will be binding upon Landlord only during the period of its ownership of the Premises and not thereafter. The term "**Landlord**" in this Lease shall mean only the owner for the time being of the Premises. Upon the transfer by such owner of its interest in the Premises, such owner shall thereupon be released and discharged from all obligations of Landlord thereafter accruing, but such obligations shall be binding during the Term upon each new owner for the duration of such owner's ownership.

**32. Inspection and Access.** Landlord and its agents, representatives, and contractors may enter the Premises at any reasonable time to inspect the Premises and to make such repairs as may be required or permitted pursuant to this Lease and for any other business purpose. Landlord and Landlord's representatives may enter the Premises during business hours on not less than 2 business days' advance written notice (except in the case of emergencies in which case no such notice shall be required and such entry may be at any time) for the purpose of effecting any such repairs, inspecting the Premises, showing the Premises to prospective purchasers and, during the last 12 months of the Term, to prospective tenants or for any other business purpose. Landlord may erect a suitable sign on the Premises stating the Premises



are available to let or that the Project is available for sale. Landlord may grant easements, make public dedications, designate Common Areas and create restrictions on or about the Premises, provided that no such easement, dedication, designation or restriction materially, adversely affects Tenant's use or occupancy of the Premises for the Permitted Use. At Landlord's request, Tenant shall execute such instruments as may be necessary for such easements, dedications or restrictions, provided that such instruments do not materially increase Tenant's obligations or materially decrease Tenant's rights under this Lease. Tenant shall at all times, except in the case of emergencies, have the right to escort Landlord or its agents, representatives, contractors or guests while the same are in the Premises, provided such escort does not materially and adversely affect Landlord's access rights hereunder.

**33. Security.** Tenant acknowledges and agrees that security devices and services, if any, while intended to deter crime may not in given instances prevent theft or other criminal acts and that Landlord is not providing any security services with respect to the Premises. Tenant agrees that Landlord shall not be liable to Tenant for, and Tenant waives any claim against Landlord with respect to, any loss by theft or any other damage suffered or incurred by Tenant in connection with any unauthorized entry into the Premises or any other breach of security with respect to the Premises. Tenant shall be solely responsible for the personal safety of Tenant's officers, employees, agents, contractors, guests and invitees while any such person is in, on or about the Premises and/or the Project. Tenant shall at Tenant's cost obtain insurance coverage to the extent Tenant desires protection against such criminal acts.

**34. Force Majeure.** Except for the payment of Rent, neither Landlord nor Tenant shall be held responsible or liable for delays in the performance of its obligations hereunder when caused by, related to, or arising out of acts of God, sinkholes or subsidence, strikes, lockouts, or other labor disputes, embargoes, quarantines, weather, national, regional, or local disasters, calamities, or catastrophes, inability to obtain labor or materials (or reasonable substitutes therefor) at reasonable costs or failure of, or inability to obtain, utilities necessary for performance, governmental restrictions, orders, limitations, regulations, or controls, national emergencies, local, regional or national epidemic or pandemic, delay in issuance or revocation of permits, enemy or hostile governmental action, terrorism, insurrection, riots, civil disturbance or commotion, cyberattacks, ransomware attacks and similar events, fire or other casualty, and other causes or events beyond their reasonable control ("**Force Majeure**"). Notwithstanding anything to the contrary contained herein, in no event shall Force Majeure excuse Tenant's obligation to vacate and surrender timely the Premises in accordance with the terms and conditions of this Lease.

**35. Brokers.** Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with this transaction and that no Broker brought about this transaction, other than Jones Lang LaSalle. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than Jones Lang LaSalle, claiming a commission or other form of compensation, if any, by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction.

**36. Limitation on Landlord's Liability.** NOTWITHSTANDING ANYTHING SET FORTH HEREIN OR IN ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT TO THE CONTRARY: (A) LANDLORD SHALL NOT BE LIABLE TO TENANT OR ANY OTHER PERSON FOR (AND TENANT AND EACH SUCH OTHER PERSON ASSUME ALL RISK OF) LOSS, DAMAGE OR INJURY, WHETHER ACTUAL OR CONSEQUENTIAL TO: TENANT'S PERSONAL PROPERTY OF EVERY KIND AND DESCRIPTION, INCLUDING, WITHOUT LIMITATION TRADE FIXTURES, EQUIPMENT, INVENTORY, SCIENTIFIC RESEARCH, SCIENTIFIC EXPERIMENTS, LABORATORY ANIMALS, PRODUCT, SPECIMENS, SAMPLES, AND/OR SCIENTIFIC, BUSINESS, ACCOUNTING AND OTHER RECORDS OF EVERY KIND AND DESCRIPTION KEPT AT THE PREMISES AND ANY AND ALL INCOME DERIVED OR DERIVABLE THEREFROM; (B) THERE SHALL BE NO PERSONAL RECOURSE TO LANDLORD FOR ANY ACT OR OCCURRENCE IN, ON OR ABOUT THE PREMISES OR ARISING IN ANY WAY UNDER THIS LEASE OR ANY OTHER AGREEMENT BETWEEN LANDLORD AND TENANT WITH RESPECT TO THE SUBJECT MATTER HEREOF AND ANY LIABILITY OF LANDLORD HEREUNDER SHALL BE STRICTLY LIMITED SOLELY TO LANDLORD'S INTEREST IN THE PROJECT OR ANY PROCEEDS FROM SALE OR CONDEMNATION THEREOF AND ANY INSURANCE PROCEEDS



PAYABLE IN RESPECT OF LANDLORD'S INTEREST IN THE PROJECT OR IN CONNECTION WITH ANY SUCH LOSS; AND (C) IN NO EVENT SHALL ANY PERSONAL LIABILITY BE ASSERTED AGAINST LANDLORD IN CONNECTION WITH THIS LEASE NOR SHALL ANY RECOURSE BE HAD TO ANY OTHER PROPERTY OR ASSETS OF LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, MEMBERS, EMPLOYEES, AGENTS OR CONTRACTORS. UNDER NO CIRCUMSTANCES SHALL LANDLORD OR ANY OF LANDLORD'S OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR CONTRACTORS BE LIABLE FOR INJURY TO TENANT'S BUSINESS OR FOR ANY LOSS OF INCOME OR PROFIT THEREFROM.

Tenant acknowledges and agrees that measures and/or services implemented at the Project, if any, intended to encourage social distancing, promote and protect health and physical well-being and/or intended to limit the spread of Infectious Conditions, may not prevent the spread of such Infectious Conditions. Neither Landlord nor any Landlord Indemnified Parties shall have any liability and Tenant waives any claims against Landlord and the Landlord Indemnified Parties with respect to any loss, damage or injury in connection with (x) the implementation, or failure of Landlord or any Landlord Indemnified Parties to implement, any measures and/or services at the Project intended to encourage social distancing, promote and protect health and physical well-being and/or intended to limit the spread of Infectious Conditions, or (y) the failure of any measures and/or services implemented at the Project, if any, to limit the spread of any Infectious Conditions.

**37. Severability.** If any clause or provision of this Lease is illegal, invalid or unenforceable under present or future laws, then and in that event, it is the intention of the parties hereto that the remainder of this Lease shall not be affected thereby. It is also the intention of the parties to this Lease that in lieu of each clause or provision of this Lease that is illegal, invalid or unenforceable, there be added, as a part of this Lease, a clause or provision as similar in effect to such illegal, invalid or unenforceable clause or provision as shall be legal, valid and enforceable.

**38. Signs; Exterior Appearance.** Tenant shall not, without the prior written consent of Landlord, which may be granted or withheld in Landlord's reasonable discretion: (i) attach any awnings, exterior lights, decorations, balloons, flags, pennants, banners, painting or other projection to any outside wall of the Project, (ii) use any curtains, blinds, shades or screens other than Landlord's standard window coverings which are visible from the outside the Premises, (iii) coat or otherwise sunscreen the interior or exterior of any windows, (iv) place any bottles, parcels, or other articles on the window sills, (v) place any equipment, furniture or other items of personal property on any exterior balcony, or (vi) paint, affix or exhibit on any part of the Premises or the Project any signs, notices, window or door lettering, placards, decorations, or advertising media of any type which can be viewed from the exterior of the Premises. Suite entry signage shall be inscribed, painted or affixed for Tenant by Landlord at the sole cost and expense of Tenant, and shall be of a size, color and type acceptable to Landlord and Tenant's name and suite number shall be included on the Building lobby directory. Nothing may be placed on the exterior of corridor walls or corridor doors other than Landlord's standard lettering. The Building lobby directory shall be provided exclusively for the display of the name and location of tenants.

Tenant shall also have the non-exclusive right to display, at Landlord's cost and expense, a sign bearing Tenant's name and/or logo on the monument sign serving the Building in a location designated by Landlord (the "**Monument Sign**"). Notwithstanding the foregoing, Tenant acknowledges and agrees that Tenant's signage on the Monument Sign including, without limitation, the size, color and type, shall be subject to Landlord's prior written approval and shall be consistent with Landlord's signage program at the Project and applicable Legal Requirements. Landlord shall be responsible, at no cost to Tenant, for the design, permitting, fabrication, installation, and maintenance of Tenant's Monument Sign. Tenant shall be responsible, at Tenant's sole cost and expense, for the removal of Tenant's Monument Sign at the expiration or earlier termination of this Lease and for the repair of all damage resulting from such removal.

Tenant shall also have the non-exclusive right to display 1 sign bearing Tenant's name and/or logo on the Building-top in a location designated by Landlord (the "**Building Sign**"). Notwithstanding the foregoing, Tenant acknowledges and agrees that Tenant's Building Sign including, without limitation, the

size, color and type, shall be subject to Landlord's prior written approval and shall be consistent with Landlord's signage program at the Project and applicable Legal Requirements. Landlord shall be responsible, at no cost to Tenant, for the design, permitting, fabrication, installation, and maintenance of Tenant's Building Sign. Tenant shall be responsible, at Tenant's sole cost and expense, for the removal of Tenant's Building Sign at the expiration or earlier termination of this Lease and for the repair of all damage resulting from such removal. Tenant shall have the right to approve the design of the Building Sign prior to installation of the same by Landlord.

### 39. Right to Expand.

(a) **Expansion in the Building.** Subject to the rights of existing tenants of the Project as of the Effective Date and to the terms of this Section 39(a), Tenant shall have the ongoing right during the Base Term, but not the obligation, subject to the terms of this Section 39(a), to expand the Premises (the "**Expansion Right**") to include the Expansion Space upon the terms and conditions in this Section 39. For purposes of this Section 39(a), "**Expansion Space**" shall mean the balance of the Building which is not occupied by a tenant or which is occupied by a then-existing tenant whose lease is expiring within 36 months or less and such tenant does not wish to renew (whether or not such tenant has a right to renew) its occupancy of such space. If all or a portion of the Expansion Space becomes available, Landlord shall, at such time as Landlord shall elect so long as Tenant's rights hereunder are preserved, deliver to Tenant written notice (the "**Expansion Notice**") of the availability of such Expansion Space, together with the terms and conditions on which Landlord is prepared to lease Tenant such Expansion Space. For the avoidance of doubt, Tenant shall be required to exercise its right under this Section 39(a) with respect to all of the space described in the Expansion Notice ("**Identified Space**"). Tenant acknowledges and agrees that the term of this Lease with respect to the Identified Space may not be co-terminus with the Term of this Lease with respect to the then-existing Premises. Tenant shall have 10 business days following receipt of the Expansion Notice to deliver to Landlord written notification of Tenant's exercise of the Expansion Right ("**Exercise Notice**") with respect to the Identified Space. If Tenant does not deliver an Exercise Notice to Landlord within such 10 business day period, then Tenant shall be deemed to have waived its rights under this Section 39(a) to lease the Identified Space, and Landlord shall have the right to lease the Identified Space to any third party on any terms and conditions acceptable to Landlord. Notwithstanding anything to the contrary contained herein, Tenant shall have no right to exercise the Expansion Right and the provisions of this Section 39(a) shall no longer apply after the date that is 12 months prior to the expiration of the Base Term if Tenant has not exercised its Extension Right pursuant to Section 40.

(b) **Amended Lease.** If: (i) Tenant fails to timely deliver an Exercise Notice, or (ii) after the expiration of a period of 10 business days after Landlord's delivery to Tenant of a lease amendment for Tenant's lease of the Identified Space, no lease amendment for the Identified Space acceptable to both parties each in their reasonable discretion after using diligent good faith efforts negotiate the same, has been executed, Tenant shall, notwithstanding anything to the contrary contained herein, be deemed, subject to its ongoing right under Section 39(a) above, to have waived its right to lease such Identified Space.

(c) **Exceptions.** Notwithstanding the above, the Expansion Right shall not be in effect and may not be exercised by Tenant:

(i) during any period of time that Tenant is in default under any provision of this Lease (after receipt of written notice and beyond any applicable notice and cure periods); or

(ii) during any period that Tenant (and any transferee pursuant to a Permitted Assignment) is occupying less than 100% of the Premises; or

(iii) if Tenant has been in default (after receipt of written notice and beyond any applicable notice and cure periods) under any provision of this Lease 3 or more times, whether or not such defaults have been cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Expansion Right.

(d) **Termination.** The Expansion Right shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely delivery of an Exercise Notice if, after such delivery, but prior to the commencement date of the lease of such Identified Space, (i) Tenant fails to cure any default by Tenant under this Lease prior to the expiration or any applicable notice and cure periods; or (ii) Tenant has Defaulted (beyond any applicable notice and cure periods) 3 or more times during the period commencing on the date of delivery of an Exercise Notice through the date of the commencement of the lease of the Identified Space, whether or not such Defaults have been cured.

(e) **Subordinate.** Tenant's rights in connection with the Expansion Right are and shall be subject to and subordinate to any expansion rights existing as of the Effective Date.

(f) **Rights Personal.** The Expansion Right is personal to Tenant and is not assignable without Landlord's prior written consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in this Lease, except that they may be assigned in connection with any assignment of this Lease that constitutes a Permitted Assignment.

(g) **No Extensions.** The period of time within which the Expansion Right may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise the Expansion Right.

**40. Right to Extend Term.** Tenant shall have the right to extend the Term of this Lease upon the following terms and conditions:

(a) **Extension Rights.** Tenant shall have 2 consecutive rights (each, an "**Extension Right**") to extend the term of this Lease for 36 months each (each, an "**Extension Term**") on the same terms and conditions as this Lease (other than with respect to Base Rent) by giving Landlord written notice of its election to exercise each Extension Right at least 12 months prior, and no earlier than 15 months prior, to the expiration of the Base Term of this Lease or the expiration of the prior Extension Term.

Upon the commencement of each Extension Term, Base Rent shall be payable at the Market Rate (as defined below). Base Rent shall thereafter be adjusted on each annual anniversary of the commencement of such Extension Term by a percentage as determined by Landlord and agreed to by Tenant at the time the Market Rate is determined. As used herein, "**Market Rate**" shall mean the rate that comparable landlords of comparable buildings have accepted in current transactions from non-equity (i.e., not being offered equity in the buildings) and nonaffiliated tenants of similar financial strength for space of comparable size, quality (including all Tenant Improvements, Alterations and other improvements) and floor height in Class A laboratory/office buildings in the San Mateo/San Carlos/Redwood City area for a comparable term, with the determination of the Market Rate to take into account all relevant factors, including tenant inducements, views, available amenities (including, without limitation, the Project Amenities, age of the Building, age of mechanical systems serving the Premises), parking costs, leasing commissions, allowances or concessions, if any. Notwithstanding the foregoing, the Market Rate shall in no event be less than the Base Rent payable as of the date immediately preceding the commencement of such Extension Term increased by the Rent Adjustment Percentage multiplied by such Base Rent. In addition, Landlord may impose a market rent for the parking rights provided hereunder.

If, on or before the date which is 240 days prior to the expiration of the Base Term of this Lease or the prior Extension Term, as applicable, Tenant has not agreed with Landlord's determination of the Market Rate and the rent escalations during the Extension Term after negotiating in good faith, Tenant shall be deemed to have elected arbitration as described in Section 40(b). Tenant acknowledges and agrees that, if Tenant has elected to exercise the Extension Right by delivering notice to Landlord as required in this Section 40(a), Tenant shall have no right thereafter to rescind or elect not to extend the term of this Lease for the Extension Term.

(b) **Arbitration.**

(i) Within 10 days of Tenant's notice to Landlord of its election (or deemed election) to arbitrate Market Rate and escalations, each party shall deliver to the other a proposal containing the Market Rate and escalations that the submitting party believes to be correct ("**Extension Proposal**"). If either party fails to timely submit an Extension Proposal, the other party's submitted proposal shall determine the Base Rent and escalations for the Extension Term. If both parties submit Extension Proposals, then Landlord and Tenant shall meet within 7 days after delivery of the last Extension Proposal and make a good faith attempt to mutually appoint a single Arbitrator (and defined below) to determine the Market Rate and escalations. If Landlord and Tenant are unable to agree upon a single Arbitrator, then each shall, by written notice delivered to the other within 10 days after the meeting, select an Arbitrator. If either party fails to timely give notice of its selection for an Arbitrator, the other party's submitted proposal shall determine the Base Rent for the Extension Term. The 2 Arbitrators so appointed shall, within 5 business days after their appointment, appoint a third Arbitrator. If the 2 Arbitrators so selected cannot agree on the selection of the third Arbitrator within the time above specified, then either party, on behalf of both parties, may request such appointment of such third Arbitrator by application to any state court of general jurisdiction in the jurisdiction in which the Premises are located, upon 10 days prior written notice to the other party of such intent.

(ii) The decision of the Arbitrator(s) shall be made within 30 days after the appointment of a single Arbitrator or the third Arbitrator, as applicable. The decision of the single Arbitrator shall be final and binding upon the parties. The average of the two closest Arbitrators in a three Arbitrator panel shall be final and binding upon the parties. Each party shall pay the fees and expenses of the Arbitrator appointed by or on behalf of such party and the fees and expenses of the third Arbitrator shall be borne equally by both parties. If the Market Rate and escalations are not determined by the first day of the Extension Term, then Tenant shall pay Landlord Base Rent in an amount equal to the Base Rent in effect immediately prior to the Extension Term and increased by the Rent Adjustment Percentage until such determination is made. After the determination of the Market Rate and escalations, the parties shall make any necessary adjustments to such payments made by Tenant. Landlord and Tenant shall then execute an amendment recognizing the Market Rate and escalations for the Extension Term.

(iii) An "**Arbitrator**" shall be any person appointed by or on behalf of either party or appointed pursuant to the provisions hereof and: (i) shall be (A) a member of the American Institute of Real Estate Appraisers with not less than 10 years of experience in the appraisal of improved office and high tech industrial real estate in the San Francisco peninsula area, or (B) a licensed commercial real estate broker with not less than 15 years' experience representing landlords and/or tenants in the leasing of high tech or life sciences space in the San Francisco peninsula area, (ii) devoting substantially all of their time to professional appraisal or brokerage work, as applicable, at the time of appointment and (iii) be in all respects impartial and disinterested.

(c) **Exceptions.** Notwithstanding anything set forth above to the contrary, the Extension Rights shall not be in effect and Tenant may not exercise the Extension Rights:

(i) during any period of time that Tenant is in default under any provision of this Lease (after receipt of written notice and beyond any applicable notice and cure periods); or

(ii) during any period that Tenant (and any transferee pursuant to a Permitted Assignment) is occupying less than 100% of the Premises; or

(iii) if Tenant has been in default (after receipt of written notice and beyond any applicable notice and cure periods) under any provision of this Lease 3 or more times, whether or not such defaults have been cured, during the 12 month period prior to the date on which Tenant seeks to exercise the Extension Right.

(d) **Rights Personal.** The Extension Rights are personal to Tenant and is/are not assignable without Landlord's prior written consent, which may be granted or withheld in Landlord's sole discretion separate and apart from any consent by Landlord to an assignment of Tenant's interest in this Lease, except that they may be assigned in connection with any assignment of this Lease that constitutes a Permitted Assignment of this Lease.

(e) **No Extensions.** The period of time within which the Extension Rights may be exercised shall not be extended or enlarged by reason of Tenant's inability to exercise such Extension Rights.

(f) **Termination.** The Extension Rights shall, at Landlord's option, terminate and be of no further force or effect even after Tenant's due and timely exercise of an Extension Right, if, after such exercise, but prior to the commencement date of the Extension Term, (i) Tenant fails to timely cure any Default by Tenant under this Lease (beyond any applicable notice and cure periods); or (ii) Tenant has Defaulted (beyond any applicable notice and cure periods) 3 or more times during the period commencing on the date of the exercise of such Extension Right to the date of the commencement of the Extension Term, whether or not such Defaults have been cured.

#### 41. Intentionally Omitted.

#### 42. Miscellaneous.

(a) **Notices.** All notices or other communications between the parties shall be in writing and shall be delivered by (i) reputable overnight guaranty courier, (ii) hand delivery with signature confirming receipt, or (iii) email transmission to the email address set forth in the Basic Lease Provisions for the applicable party, which email includes in the subject line (x) the Project address, (y) Tenant name and (z) "NOTICE UNDER LEASE" in all caps, provided a hard copy of any email notice is also sent the same day by one of the delivery methods provided in sub-sections (i) or (ii) (each, a "**Follow Up Notice**"). Notices delivered pursuant to the delivery methods provided in sub-sections (i) or (ii) shall be deemed duly given when actually received by the addressee or when delivery thereof is refused. Notices delivered via email and sent during the hours of 8:00 a.m. and 3:00 p.m. PST shall be deemed duly given on the day sent; provided, however, that any email notice delivered on a Saturday, Sunday or legal holiday observed in the State of California, or after 3:00 p.m. PST shall be deemed given on the next day that is not a Saturday, Sunday or legal holiday observed in the State of California. For the avoidance of doubt, for an email notice to be effective as provided in the immediately preceding sentence, a Follow Up Notice must be delivered to the addressee of the email notice within 48 hours of the date that the email notice is delivered. If a Follow Up Notice is not received within such 48-hour period, actual notice will be deemed to have been given on the date that the Follow Up Notice is delivered rather than on the date of delivery of the email notice. Notwithstanding anything to the contrary contained herein, notice sent via email shall in no event constitute a notice hereunder if the sender receives notice or otherwise has knowledge that the email notice was not properly transmitted or otherwise received by the addressee. All notices shall be delivered to the parties at their addresses set forth in the Basic Lease Provisions. Landlord and Tenant may from time to time by written notice to the other designate another address for receipt of future notices.

(b) **Joint and Several Liability.** If and when included within the term "**Tenant**," as used in this instrument, there is more than one person or entity, each shall be jointly and severally liable for the obligations of Tenant.

(c) **Financial Information.** Tenant shall furnish to Landlord true and complete copies of (i) upon Landlord's written request on an annual basis, Tenant's most recent audited annual financial statements, provided, however, that Tenant shall not be required to deliver to Landlord such annual financial statements for any particular year sooner than the date that is 90 days after the end of each of Tenant's fiscal years during the Term, (ii) upon Landlord's written request on a quarterly basis, Tenant's most recent unaudited quarterly financial statements; provided, however, that Tenant shall not be required to deliver to Landlord such quarterly financial statements for any particular quarter sooner than the date that is 45 days after the end of each of Tenant's fiscal quarters during the Term, (iii) upon Landlord's written request from

time to time, updated business plans, including cash flow projections and/or pro forma balance sheets and income statements, all of which shall be treated by Landlord as confidential information belonging to Tenant, (iv) upon Landlord's written request from time to time, corporate brochures and/or profiles prepared by Tenant for prospective investors, and (v) upon Landlord's written request from time to time, any other financial information or summaries that Tenant typically provides to its lenders or shareholders. Notwithstanding anything to the contrary contained in this Lease, Landlord's written request for financial information pursuant to this Section 42(c) may be delivered to Tenant via email. So long as Tenant is a "public company" and its financial information is publicly available, then the foregoing delivery requirements of this Section 42(c) shall not apply.

(d) **Recordation.** Neither this Lease nor a memorandum of lease shall be filed by or on behalf of Tenant in any public record. Landlord may prepare and file, and upon request by Landlord Tenant will execute, a memorandum of lease.

(e) **Interpretation.** The normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Lease or any exhibits or amendments hereto. Words of any gender used in this Lease shall be held and construed to include any other gender, and words in the singular number shall be held to include the plural, unless the context otherwise requires. The captions inserted in this Lease are for convenience only and in no way define, limit or otherwise describe the scope or intent of this Lease, or any provision hereof, or in any way affect the interpretation of this Lease.

(f) **Not Binding Until Executed.** The submission by Landlord to Tenant of this Lease shall have no binding force or effect, shall not constitute an option for the leasing of the Premises, nor confer any right or impose any obligations upon either party until execution of this Lease by both parties.

(g) **Limitations on Interest.** It is expressly the intent of Landlord and Tenant at all times to comply with applicable law governing the maximum rate or amount of any interest payable on or in connection with this Lease. If applicable law is ever judicially interpreted so as to render usurious any interest called for under this Lease, or contracted for, charged, taken, reserved, or received with respect to this Lease, then it is Landlord's and Tenant's express intent that all excess amounts theretofore collected by Landlord be credited on the applicable obligation (or, if the obligation has been or would thereby be paid in full, refunded to Tenant), and the provisions of this Lease immediately shall be deemed reformed and the amounts thereafter collectible hereunder reduced, without the necessity of the execution of any new document, so as to comply with the applicable law, but so as to permit the recovery of the fullest amount otherwise called for hereunder.

(h) **Choice of Law.** Construction and interpretation of this Lease shall be governed by the internal laws of the state in which the Premises are located, excluding any principles of conflicts of laws.

(i) **Time.** Time is of the essence as to the performance of Tenant's obligations under this Lease.

(j) **OFAC.** Tenant and all beneficial owners of Tenant are currently (a) in compliance with and shall at all times during the Term of this Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("OFAC") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "OFAC Rules"), (b) not listed on, and shall not during the term of this Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List, or the Sectoral Sanctions Identification List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.



(k) **Incorporation by Reference.** All exhibits and addenda attached hereto are hereby incorporated into this Lease and made a part hereof. If there is any conflict between such exhibits or addenda and the terms of this Lease, such exhibits or addenda shall control.

(l) **Entire Agreement.** This Lease, including the exhibits attached hereto, constitutes the entire agreement between Landlord and Tenant pertaining to the subject matter hereof and supersedes all prior and contemporaneous agreements, understandings, letters of intent, negotiations and discussions, whether oral or written, of the parties, and there are no warranties, representations or other agreements, express or implied, made to either party by the other party in connection with the subject matter hereof except as specifically set forth herein.

(m) **No Accord and Satisfaction.** No payment by Tenant or receipt by Landlord of a lesser amount than the monthly installment of Base Rent or any Additional Rent will be other than on account of the earliest stipulated Base Rent and Additional Rent, nor will any endorsement or statement on any check or letter accompanying a check for payment of any Base Rent or Additional Rent be an accord and satisfaction. Landlord may accept such check or payment without prejudice to Landlord's right to recover the balance of such Rent or to pursue any other remedy provided in this Lease.

(n) **Landlord's Proprietary Operations.** Tenant acknowledges that Landlord has informed Tenant that Landlord has been made aware of third parties contacting tenants of Landlord and Landlord's affiliates requesting information regarding Landlord's business operations including, without limitation, the type and quality of services provided by Landlord and its affiliates to such tenants. Tenant further acknowledges that Landlord's business operations are proprietary to Landlord and that the sharing by tenants of information regarding Landlord's business operations with third parties may result in damages to Landlord which would be extremely difficult or impossible to ascertain. Except as expressly provided in the following sentence, absent prior written consent from Landlord, Tenant shall hold confidential and will not disclose to third parties, information regarding the Building Systems, controls, equipment, programming, vendors, and specialized amenities of Landlord. Notwithstanding the foregoing, Tenant may disclose such information (v) to Tenant's brokers in connection with any assignment or sublease of this Lease and/or any portion of the Premises, (w) to Tenant's affiliates, provide that Tenant advises Tenant's affiliates such information is confidential, (x) to third parties as reasonably required to facilitate Tenant's business and operations within the Premises (which may include disclosure to successors of Tenant's interest in the Lease, subtenants and licensees), provided that Tenant deliver written notice to all parties requiring them to treat such information as confidential and not disclose to other parties, (y) for compliance with a valid order of a court or other governmental body having jurisdiction, or any law, statute, or regulation, or as otherwise required by law, and (z) in connection with Tenant's enforcement of its rights under this Lease. For avoidance of doubt, disclosure of (i) information ascertainable from signage at the Project, (ii) the mere existence of a restaurant, fitness center or conference center at the Project, or (iii) any information contained in Landlord's marketing materials for the Project, will not violate the disclosure limitations set forth in this paragraph.

(o) **Hazardous Activities.** Notwithstanding any other provision of this Lease, Landlord, for itself and its employees, agents and contractors, reserves the right to refuse to perform any repairs or services in any portion of the Premises which, pursuant to Tenant's routine safety guidelines, practices or custom or prudent industry practices, require any form of protective clothing or equipment other than safety glasses, lab coats and/or gloves. In any such case, Tenant shall contract with parties who are acceptable to Landlord, in Landlord's reasonable discretion, for all such repairs and services, and Landlord shall, to the extent required, equitably adjust Tenant's Share of Operating Expenses in respect of such repairs or services to reflect that Landlord is not providing such repairs or services to Tenant.

(p) **Redevelopment of Project.** Tenant acknowledges that Landlord, in its sole discretion, may from time to time, subject to the terms of the fifth sentence of Section 1 of this Lease, expand, renovate and/or reconfigure the Project as the same may exist from time to time and, in connection therewith or in addition thereto, as the case may be, from time to time without limitation: (a) change the shape, size, location, number and/or extent of any improvements, buildings, structures, lobbies, hallways, entrances,

exits, parking and/or parking areas relative to any portion of the Project; (b) modify, eliminate and/or add any buildings, improvements, and parking structure(s) either above or below grade, to the Project, the Common Areas and/or any other portion of the Project and/or make any other changes thereto affecting the same; and (c) make any other changes, additions and/or deletions in any way affecting the Project and/or any portion thereof as Landlord may elect from time to time, including without limitation, additions to and/or deletions from the land comprising the Project, the Common Areas and/or any other portion of the Project, provided that such actions do not materially adversely affect Tenant's use of or access to the Premises for the Permitted Use. Tenant acknowledges and agrees that construction noise, vibrations and dust associated with normal construction activities in connection with any redevelopment of the Project are to be expected during the course of such construction. Notwithstanding anything to the contrary contained in this Lease, Tenant shall have no right to seek damages (including abatement of Rent) or to cancel or terminate this Lease because of any proposed changes, expansion, renovation or reconfiguration of the Project nor shall Tenant have the right to restrict, inhibit or prohibit any such changes, expansion, renovation or reconfiguration; provided, however, Landlord shall not change the size, dimensions, location or Tenant's Permitted Use of the Premises or materially adversely impact Tenant's use and occupancy of the Premises and/or access to parking at the Project, other than on a temporary basis while construction and related work may be ongoing.

(q) **EV Charging Stations.** To the extent that the Project is not exempt Section 1952.7 of the California Civil Code, Landlord shall not unreasonably withhold its consent to Tenant's written request to install 1 or more electric vehicle car charging stations ("**EV Stations**") in the parking area serving the Project; provided, however, that Tenant complies with all reasonable requirements, standards, rules and regulations which may be imposed by Landlord, at the time Landlord's consent is granted, in connection with Tenant's installation, maintenance, repair and operation of such EV Stations, which may include, without limitation, the charge to Tenant of a reasonable monthly rental amount for the parking spaces used by Tenant for such EV Stations, Landlord's designation of the location of Tenant's EV Stations, and Tenant's payment of all costs whether incurred by Landlord or Tenant in connection with the installation, maintenance, repair and operation of each Tenant's EV Station(s). Nothing contained in this paragraph is intended to increase the number of parking spaces which Tenant is otherwise entitled to use at the Project under Section 10 of this Lease nor impose any additional obligations on Landlord with respect to Tenant's parking rights at the Project.

(r) **California Accessibility Disclosure.** For purposes of Section 1938(a) of the California Civil Code, Landlord hereby discloses to Tenant, and Tenant hereby acknowledges, that the Project has not undergone inspection by a Certified Access Specialist (CASp). In addition, the following notice is hereby provided pursuant to Section 1938(e) of the California Civil Code: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises." In furtherance of and in connection with such notice: (i) Tenant, having read such notice and understanding Tenant's right to request and obtain a CASp inspection, hereby elects not to obtain such CASp inspection and forever waives its rights to obtain a CASp inspection with respect to the Premises, Building and/or Project to the extent permitted by Legal Requirements; and (ii) if the waiver set forth in clause (i) hereinabove is not enforceable pursuant to Legal Requirements, then Landlord and Tenant hereby agree as follows (which constitutes the mutual agreement of the parties as to the matters described in the last sentence of the foregoing notice): (A) Tenant shall have the one-time right to request for and obtain a CASp inspection, which request must be made, if at all, in a written notice delivered by Tenant to Landlord; (B) any CASp inspection timely requested by Tenant shall be conducted (1) at a time mutually agreed to by Landlord and Tenant, (2) in a professional manner by a CASp designated by Landlord and without any testing that would damage the Premises, Building or Project in any way, and (3) at Tenant's sole cost and expense, including, without limitation, Tenant's payment of the fee for such



CASp inspection, the fee for any reports prepared by the CASp in connection with such CASp inspection (collectively, the “CASp Reports”) and all other costs and expenses in connection therewith; (C) the CASp Reports shall be delivered by the CASp simultaneously to Landlord and Tenant; (D) Tenant, at its sole cost and expense, shall be responsible for making any improvements, alterations, modifications and/or repairs to or within the Premises to correct violations of construction-related accessibility standards including, without limitation, any violations disclosed by such CASp inspection; and (E) if such CASp inspection identifies any improvements, alterations, modifications and/or repairs necessary to correct violations of construction-related accessibility standards relating to those items of the Building and Project located outside the Premises that are Landlord’s obligation to repair as set forth in this Lease, then Landlord shall perform such improvements, alterations, modifications and/or repairs as and to the extent required by Legal Requirements to correct such violations, and Tenant shall reimburse Landlord for the cost of such improvements, alterations, modifications and/or repairs within 30 days after Tenant’s receipt of an invoice therefor from Landlord.

(s) **Shuttle Services.** Landlord and affiliates of Landlord plan to provide a campus shuttle service for the Project and other buildings in the vicinity of the Project that are owned by affiliates of Landlord (the “Shuttle Service”); provided, however, that neither Landlord nor any affiliate of Landlord shall be obligated to provide the Shuttle Service (or, once the Shuttle Service has commenced, to continue providing the Shuttle Service for any specific period of time) or to cause the Shuttle Service to follow any specific route, make any specific stops, or adhere to any specific schedule or hours of operation. If Landlord and affiliates of Landlord actually commence operation of the Shuttle Service, (i) Landlord shall give Tenant written notice of the date such operation will commence (“Shuttle Services Commencement Date”) and the planned route, stops, schedule, and hours of operation, (ii) Landlord shall permit Tenant’s employees actually employed at the Project to use the Shuttle Service, and (iii) regardless of whether Tenant’s employees use the Shuttle Services, commencing on later to occur of (x) the Shuttle Services Commencement Date, or the Rent Commencement Date, through the earlier of the expiration of the Term or the date that Landlord permanently ceases to provide Shuttle Service, Operating Expenses shall include the cost of provision the Shuttle Service (the “Shuttle Service Costs”). Tenant acknowledges and agrees that Landlord has not made any representations or warranties regarding the commencement or continued availability of the Shuttle Service and that Tenant is not entering into this Lease with an expectation that the Shuttle Service shall commence or continue to be available to Tenant throughout the Term.

(t) **Counterparts.** This Lease may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Lease and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

(u) **Prevailing Party’s Fees.** In the event that either party should bring suit or commence any suit or proceeding related to this Lease against the other party, then all reasonable costs and expenses, including reasonable attorneys’ fees and expert fees, incurred by the prevailing party relating to such legal action shall be paid by the other party, which obligation on the part of the other party shall be deemed to have accrued on the date of the commencement of such action and shall be enforceable whether or not the action is prosecuted to judgment.

[ Signatures on next page ]



IN WITNESS WHEREOF, Landlord and Tenant have executed this Lease as of the day and year first above written.

**TENANT:**

**CARGO THERAPEUTICS, INC.,**  
a Delaware corporation

By: /s/ Gina Chapman  
Name: Gina Chapman  
Its: CEO

X I hereby certify that the signature, name, and title above are my signature, name and title

and

By: /s/ Anup Radhakrishnan  
Name: Anup Radhakrishnan  
Its: CFO

X I hereby certify that the signature, name, and title above are my signature, name and title

**LANDLORD:**

**ARE-SAN FRANCISCO NO. 63, LLC,**  
a Delaware limited liability company

By: Alexandria Real Estate Equities, L.P.,  
a Delaware limited partnership,  
managing member

By: ARE-QRS Corp.,  
a Maryland corporation,  
general partner

By: /s/ Kristen Childs  
Its: Vice President-Real Estate

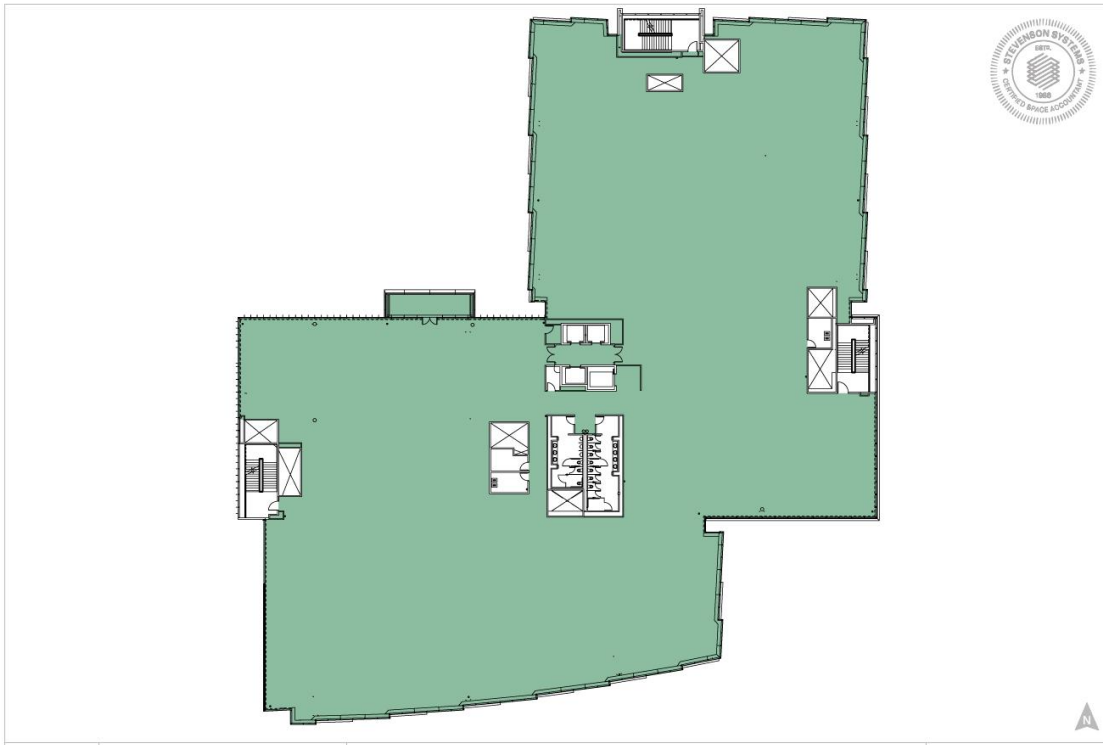
**EXHIBIT A TO LEASE**  
**DESCRIPTION OF PREMISES**



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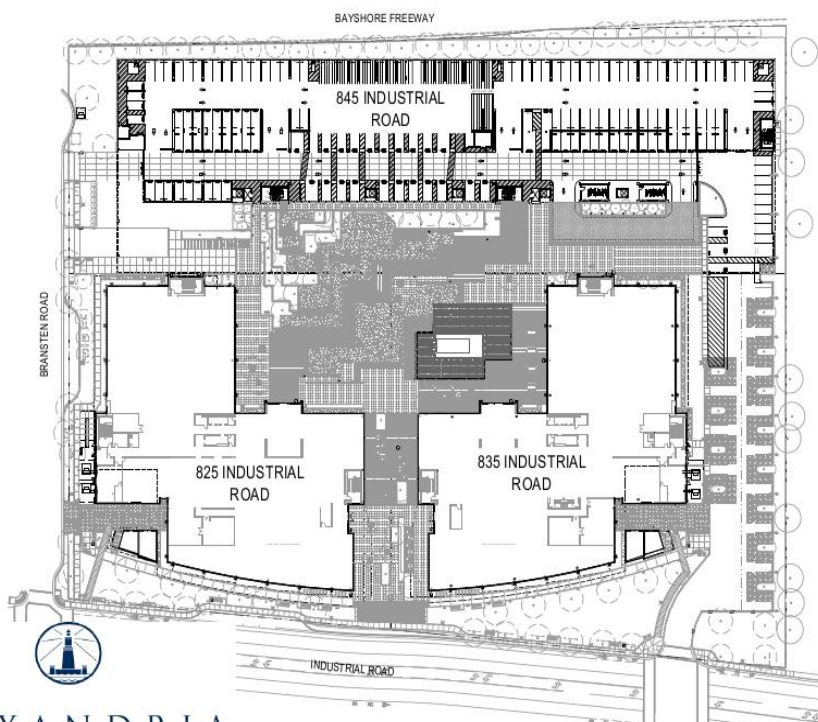
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EXHIBIT B TO LEASE

DESCRIPTION OF PROJECT



Area Tabulations for  
**Alexandria Properties**  
825-835 Industrial Road  
San Carlos, CA



DATE: April 2019

**Site Plan**

PROJECT NO: 17447101

**ALEXANDRIA**

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**EXHIBIT C TO LEASE**

**INTENTIONALLY OMITTED**

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EXHIBIT D TO LEASE

ACKNOWLEDGMENT OF COMMENCEMENT DATE

This ACKNOWLEDGMENT OF COMMENCEMENT DATE is made this \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_, between ARE-SAN FRANCISCO NO. 63, LLC, a Delaware limited liability company ("Landlord"), and CARGO THERAPEUTICS, INC., a Delaware corporation ("Tenant"), and is attached to and made a part of the Lease dated \_\_\_\_\_, 2023 (the "Lease"), by and between Landlord and Tenant. Any initially capitalized terms used but not defined herein shall have the meanings given them in the Lease.

Landlord and Tenant hereby acknowledge and agree, for all purposes of the Lease, that the Commencement Date of the Base Term of the Lease is \_\_\_\_\_, \_\_\_\_\_, the Rent Commencement Date is \_\_\_\_\_, \_\_\_\_\_, and the termination date of the Base Term of the Lease shall be 11:59 p.m. on \_\_\_\_\_, \_\_\_\_\_. In case of a conflict between the terms of the Lease and the terms of this Acknowledgment of Commencement Date, this Acknowledgment of Commencement Date shall control for all purposes.

IN WITNESS WHEREOF, Landlord and Tenant have executed this ACKNOWLEDGMENT OF COMMENCEMENT DATE to be effective on the date first above written.

TENANT:

CARGO THERAPEUTICS, INC.,
a Delaware corporation

By:
Name:
Its:

I hereby certify that the signature, name, and title above are my signature, name and title

LANDLORD:

ARE-SAN FRANCISCO NO. 63, LLC,
a Delaware limited liability company

By: Alexandria Real Estate Equities, L.P.,
a Delaware limited partnership,
managing member

By: ARE-QRS Corp.,
a Maryland corporation,
general partner

By:
Its:



**EXHIBIT E TO LEASE**

**Rules and Regulations**

1. The sidewalk, entries, and driveways of the Project shall not be obstructed by Tenant, or any Tenant Party, or used by them for any purpose other than ingress and egress to and from the Premises.
2. Tenant shall not place any objects, including antennas, outdoor furniture, etc., in the parking areas, landscaped areas or other areas outside of its Premises, or on the roof of the Project.
3. Except for animals assisting the disabled, no animals shall be allowed in the offices, halls, or corridors in the Project.
4. Tenant shall not disturb the occupants of the Project or adjoining buildings by the use of any radio or musical instrument or by the making of loud or improper noises.
5. If Tenant desires telegraphic, telephonic or other electric connections in the Premises, Landlord or its agent will direct the electrician as to where and how the wires may be introduced; and, without such direction, no boring or cutting of wires will be permitted. Any such installation or connection shall be made at Tenant's expense.
6. Tenant shall not install or operate any steam or gas engine or boiler, or other mechanical apparatus in the Premises, except as specifically approved in the Lease. The use of oil, gas or inflammable liquids for heating, lighting or any other purpose is expressly prohibited. Explosives or other articles deemed extra hazardous shall not be brought into the Project.
7. Parking any type of recreational vehicles is specifically prohibited on or about the Project. Except for the overnight parking of operative vehicles, no vehicle of any type shall be stored in the parking areas at any time. In the event that a vehicle is disabled, it shall be removed within 48 hours. There shall be no "For Sale" or other advertising signs on or about any parked vehicle. All vehicles shall be parked in the designated parking areas in conformity with all signs and other markings. All parking will be open parking, and no reserved parking, numbering or lettering of individual spaces will be permitted except as specified by Landlord.
8. Tenant shall use commercially reasonable efforts to maintain the Premises free from rodents, insects and other pests.
9. Landlord reserves the right to exclude or expel from the Project any person who, in the judgment of Landlord, is intoxicated or under the influence of liquor or drugs or who shall in any manner do any act in violation of the Rules and Regulations of the Project.
10. Tenant shall not cause any unnecessary labor by reason of Tenant's carelessness or indifference in the preservation of good order and cleanliness. Landlord shall not be responsible to Tenant for any loss of property on the Premises, however occurring, or for any damage done to the effects of Tenant by the janitors or any other employee or person.
11. Tenant shall give Landlord prompt notice of any defects of which Tenant actually becomes aware in the water, lawn sprinkler, sewage, gas pipes, electrical lights and fixtures, heating apparatus, or any other service equipment affecting the Premises.
12. Tenant shall not permit storage outside the Premises, including without limitation, outside storage of trucks and other vehicles, or dumping of waste or refuse or permit any harmful materials to be placed in any drainage system or sanitary system in or about the Premises.

13. All moveable trash receptacles provided by the trash disposal firm for the Premises must be kept in the trash enclosure areas, if any, provided for that purpose.

14. No auction, public or private, will be permitted on the Premises or the Project.

15. No awnings shall be placed over the windows in the Premises except with the prior written consent of Landlord.

16. The Premises shall not be used for lodging, sleeping or cooking (except that Tenant may use microwave ovens, toasters and coffee makers in the Premises for the benefit of Tenant's employees and contractors in an area designated for such items, but only if the use thereof is at all times supervised by the individual using the same) or for any immoral or illegal purposes or for any purpose other than that specified in the Lease. No illegal gaming devices shall be operated in the Premises.

17. Tenant shall ascertain from Landlord the maximum amount of electrical current which can safely be used in the Premises, taking into account the capacity of the electrical wiring in the Project and the Premises and the needs of other tenants, and shall not use more than such safe capacity. Landlord's consent to the installation of electric equipment shall not relieve Tenant from the obligation not to use more electricity than such safe capacity.

18. Tenant assumes full responsibility for protecting the Premises from theft, robbery and pilferage.

19. Tenant shall not install or operate on the Premises any machinery or mechanical devices of a nature not directly related to Tenant's ordinary use of the Premises and shall keep all such machinery free of vibration, noise and air waves which may be transmitted beyond the Premises.

20. Tenant shall cause any vendors and other service providers providing regular service at the Project (including, service providers hired by Tenant to perform services with respect to the Building Systems or to perform janitorial services with respect to the Premises) hired by Tenant to perform services at the Premises or the Project to maintain in effect workers' compensation insurance as required by Legal Requirements and reasonable commercial general liability insurance with coverage amounts reasonably acceptable to Landlord. Tenant shall cause such vendors and service providers to name Landlord and Alexandria Real Estate Equities, Inc. as additional insureds under such policies and shall provide Landlord with certificates of insurance evidencing the required coverages (and showing Landlord and Alexandria Real Estate Equities, Inc. as additional insureds under such policies) prior to the applicable vendor or service provider providing any services to Tenant at the Project.

21. Neither Tenant nor any of the Tenant Parties shall have the right to photograph, videotape, film, digitally record or by any other means record, transmit and/or distribute any images, pictures or videos of all or any portion of the Premises or the Project that could identify the Project or the name of the Project, or that identify Landlord or any other tenants or any affiliates of Landlord or any other tenants. The foregoing is not meant to prohibit individual employees from taking and disseminating photos of themselves or other people within the Premises or at the Project so long as neither the Building nor any proprietary information, equipment or improvements of Landlord are included within such photos or preclude Tenant from recording the Premises or portions of the Project in which the Premises is located for security purposes with security cameras included as part of a security system installed by Tenant as an Alteration pursuant to Section 12 of the Lease.

22. Tenant shall regularly review the guidelines published by the Centers for Disease Control (CDC) and any state and/or local Governmental Authorities, and will implement the practices and procedures suggested thereby, as well as industry standard best practices, to prevent the spread of Infectious Conditions, including, without limitation, COVID-19.

23. Landlord may exclude or expel from the Project any person that is exhibiting symptoms associated with any currently known or unknown Infectious Condition.

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**EXHIBIT F TO LEASE**  
**TENANT'S PERSONAL PROPERTY**

None.

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## EXHIBIT G TO LEASE

EXISTING FF&E

Room Name	Item Name/ Description	MFR	Make and Model No.	Serial
MB RT	Scepter Automated Cell Counter	Millipore	Scepter 2.0 Automated Cell Counter	
MB RT	Nikon Eclipse TS100 Microscope	Nikon		C0013158
MB RT	Nikon Eclipse TS100 Microscope	Nikon		
MB RT	Edgertronic High Speed Camera	Edgertronic		
MB RT	PLATE INCUBATOR	Thermo Fisher	HERAtherm IMH180-S	41665974
Reagent Prep	Analytical Balance, Max. 200g	Metler-Toledo	AS220.R2	422439
Reagent Prep	Plate Sealer	Axygen	PlateMax	LAHSAXY-1301009
Reagent Prep	Micro Balance	Ohaus	SPX2202	B918598367
ProtEng Yeast	Nikon Eclipse TS100 microscope	Nikon	Eclipse TS100	
MB SELECTION	FACS SORTER (BD FACSJazz)	BD	BD FACS-Jazz	J26554900050
MICROSCOPY		Zeiss	Axio Scan.Z1	4631001065
MICROSCOPY	Pannoramic Scan	3dHISTECH	Pannoramic Scan 2	
MICROSCOPE	Nikon Nie Microscope system plus.	Nikon	Ni-E	
MICROSCOPE	Microscope system plus.	Nikon	DS-Ri2	
ProtEng Upstream	Trinocular Microscope	Nikon	Nikon Eclipse TS100	151093
Tissue Culture	Microscope	NIKON	Eclipse TS2 and one TS2R	
invitro	gentleMACS Octo Dissociator w/heaters	Miltenyi Biotec	gentleMACS Octo Dissociator with heaters	
invitro	Microscope eclipse	Nikon	TS2	
ProtEng Downstream	Azure C200 Imaging System	Azure	Azure C200	2101
Epitope ID	AKTA Pure L	Cytiva	AKTA Pure	
Epitope ID	AKTA Sample pump	AKTA	Sample pump S9	
Epitope ID	FPLC - NGC Quest™ 100 Plus Chromatography System + Comp	Bio-Rad	Bio-Rad NGC Quest™ 100 System, 7880004	center bench
Epitope ID	FPLC - autosampler	Teledyne CETAC	ASX-560 BIO-RAD	center bench w/NGC
Epitope ID	HPLC + Autosampler + Comp - Agilent (black and white one)	Agilent	1260 Infinity II	center bench under beam
CB Facs TC	Eclipse TS100 microscope / camera / PC	Nikon	Nikon, TS100/Amazon	
Clean Corridor	Hoshizaki F-801MWH Ice flaker	Hoshizaki	F-801MWH	D11242F
CB Facs Core	4 DEG	Kenmore	Kenmore- Fridge	
CB Facs Core	-20 DEG	Frigidaire	Frigidaire	
CB Facs Core	4' BSC 11-AZ (no UV)	Baker	Baker	
CB Facs Core	FLAM CAB/large		NA	
CB Facs Core	4' BSC 11-A2	Baker	Baker	
MB RT	4 DEG Refrigerator	Kenmore	--	WA44503170
MB RT	4C Refrigerator, BIRC Supplies	Danby Products	Danby Designer	11409010050
MB RT	SG504 Biosafety Cabinet	Baker	SterilGARD SG 504	114055
MB RT	BSC: SG503A-HE w/FlexAIR	Baker	SterilGARD SG503A- HE	107537
MB RT	5' CLASS 11A (Esco Master Mix hood)	ESCO	--	--
MB RT	Portable bench	72X30		
MB RT	Portable bench	60X30		
MB RT	Lab (Island) Bench, 48inx30in modular Unit	60X30	--	--
MB RT	Lab (Island) Bench, 48inx30in modular Unit	60X30	--	--

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MB RT	Lab (Island) Bench, 48inx30in modular Unit	60X30	--	--
MB RT	Lab (Island) Bench, 48inx30in modular Unit	60X30	--	--
MB RT	Lab (Island) Bench, 48inx30in modular Unit	60X30	--	--
MB RT	Lab (Island) Bench, 48inx30in modular Unit	48X30	--	--
MB RT	Lab (Island) Bench, 48inx30in modular Unit	--	--	--
MB RT	Lab (Island) Bench, 48inx30in modular Unit	--	--	--
MB RT	5' CLASS 11A (Esco Master Mix hood)	ESCO	--	--
Reagent Prep	-20 DEG Freezer	Kenmore	--	--
Reagent Prep	4 DEG Refrigerator	Kenmore	--	--
Reagent Prep	Build-in flammable cabinet			
Reagent Prep	build-in chemical cabinet			
Cryo Frz	-80 Freezer #1	Panasonic	MDF-U76VA	12077N0043
Cryo Frz	Lab Bench, 5ft, w/ shelf	--	--	--
Cryo Frz	-80 Freezer #2	Panasonic	MDF-U76VA	15107N0260
Cryo Frz	Lab Bench, 4ft, w/ shelf	--	--	--
Cryo Frz	Lab Table, 4ft			
Cryo Frz	LN2 dewar			
Cryo Frz	LN2 Sample CryoStorage Unit	Worthington	24K-CS200	30876
	Lab bench 4ft x 3ft			
	BSC	Baker	Steril Gard	
	BSC	Baker	Steril Gard	
	6ft portable lab bench with shelves			
MB Post Amp	-20 DEG Freezer	Kenmore	--	--
MB Post Amp	-20 DEG Freezer	Kenmore	--	--
MB Post Amp	-20 DEG Freezer	Semons	--	--
MB Post Amp	-20 DEG Freezer	Semons	--	--
MB Post Amp	Skinny Freezer -20C			
MB Post Amp	Skinny Fridge 4C			
MB Post Amp	Small -20 Freezer			
MB Post Amp	Fume Hood			
TS SOLV	FLAM CAB			
Rad Lab - Hot	4' BSC - Class II B2	Baker Company	BioChemGard; BCG401	137304
Rad Lab - Hot	4ft BSC - class 2	Baker Company	SterilGard III Advance; Model: SG 403	69151
	Panasonic -80C (Mouse tissues)			
TM-MB ASSAY LAB	DD DELI	Fisher	Fisher Isotemp GTFBG45CPLA	300404420
TM-MB ASSAY LAB	-20 Freezer	American Biotech Supply	ABT-HC-MFP-20	ABS-21056829-2111
TM-MB ASSAY LAB	-80 Freezer	Thermo Fisher Scientific	Thermo Fisher Scientific TSX Series TSX60086A	1124365701211023
	DD DELI			
	DD DELI			
	Combo freezer/fridge	kenmore		
	Combo freezer/fridge	kenmore		
Trans Sci	Accucold Pharmaceutical Storage 4 degree	Accucold		
ProtEng Yeast	MPR-715F combo Lab fridge/freezer	PHCBI	MPR-715F Combo	18039030
ProtEng Yeast	4' BSC	Esco	Labculture Reliant Gen 2E Class II Type A2 BSC	2020-150474
ProtEng Yeast	4C Deli Fridge	PHCBI	MPR-1412-PA	21010005



MB HELPER	4 DEG/-20 DEG	Panasonic		
MB SELECTION	4 DEG/-20 DEG			
MB SELECTION	Ice Maker			
GLASSWASH	Ice Maker	Hoshizaki	F-330BAH Cubelet Ice Maker	
GLASSWASH	Autoclave	Steris		
E coli	Lab Table			
E coli	Lab Table			
Media Prep	Milli-Q Integral 15 system	Millipore	MilliQ Integral 15 System	
outside of Upstream	Panasonic Narrower -80 freezer	Panasonic	MDF-U33V-PA Ultra Low Temp Freezer	
ProtEng Upstream	Deli Fridge double doors	PHCbi		
ProtEng Upstream	PO 4655 Class II Type A2 BSC	NuAire	NU-543-400 Nuaire	176565101216
ProtEng Upstream	4' BSC II-A2	ESCO	Class II BSC AC2-4s9	2018-125621
ProtEng Upstream	-20 DEG	Kenmore	white-box type	WB23250682
ProtEng Upstream	4 DEG	Kenmore	white-box type	WA40602545
ProtEng Upstream	6' CLASS IIA	ESCO	LA2-6A2-E-PORT	2019-140072
ProtEng Upstream	4' BSC II-A2 #2	ESCO	ESCO LA2-4A2-E-PORT AF	2020-158843
ProtEng Upstream	6' BSC II-A2 #2	ESCO	ESCO LA2-6A2-E-PORT AF	2020-159883
ProtEng Upstream	Pharmaceutical Refrigerator	Panasonic	MPR-721-PA	17020067
Tissue Culture	4 DEG	Kenmore		253.6072201
Tissue Culture	4 DEG	Kenmore		253.6072201
Tissue Culture	-20 DEG	Kenmore	253.2104241	
Tissue Culture	4' TYPE II-A2 BSC	BAKER		
Tissue Culture	Baker SterilGARD eIII (4ft)	BAKER		
Tissue Culture	4' TYPE II-A2 BSC	BAKER		
11000	4' TYPE II-A2 BSC	BAKER		
Corridor	-20 DEG AT043686	Kenmore	253.2104241	
Corridor	-80 DEG Freezer ("Clinical") AT019126	ThermoScientific	TSX60086A	1119686801190120
Corridor	-80 DEG Freezer AT043687	ThermoScientific	TSX60086A	
SHARED TC	-20 Freezer Combo	Kenmore		
Ab Inventory	PO 31274 Danby Designer 4.4 Cubic Feet Compact Refrigerator			
Target ID	Deli Fridge #1	PHCBI	MPR-1412-PA	19040042
Target ID	Deli Fridge #5	PHCBI		
Target ID	-20C Freezer	Kenmore		WB45127105
Target ID	-20C Freezer	Frigidaire		WB91563159
Ab Inventory	4' BSC	ESCO	ESCO LA2-4A2-E-PORT AF	2020-158842
invitro	Panasonic double door deli fridge	Panasonic		MPR-1411-PA
invitro	Panasonic double door deli fridge	Panasonic		MPR-1411-PA
invitro	4 DEG Fridge (this was shared between Target ID and Trans Sci)	Kenmore		253.6072201
invitro	-20 DEG Freezer	Kenmore		253.2104241
ProtEng Downstream	-80 DEG	Panasonic	MDF-U76VA-PA	17087No274
ProtEng Downstream	-20 DEG	Kenmore	Kenmore 21 cu ft	
ProtEng Downstream	DD DELI	PHCBI	MPR-1412-PA	19040044





ProtEng Downstream	4' BSC	Nuair	4'	1.18639E+11
ProtEng Downstream	PO 14591 DD DELI	PHCBI	MPR-1412-PA	
ProtEng Downstream	Water filter: Sartorius arium comfort	Sartorius	arium comfort	
Epitope ID	double door deli fridge	Panasonic		along wall w/Akta inside
Epitope ID	Combo 4C fridge and -30C freezer	PHC	MPR-715F-PA	
Epitope ID	Freezer -80C	PHC	MDF-U76VA-PA	
CB Facs TC	4' BSC	Baker	Baker, SteriGARD 404	
CB Facs TC	6' BSC CLASS 11A	Baker	Baker	
CB Facs TC	4 DEG	Whirlpool	Whirlpool - Fridge	
CB Facs TC	-20 DEG (small)	Kenmore	Kenmore	
CB Facs TC	Lab Bench			
	-20 DEG Freezer	Kenmore	--	--
MB RT	-20 DEG Freezer	Kenmore	--	--
MB RT	-20 DEG for cDNA/RT plate storage (IRC)	Kenmore	255.2970201	BLR2127118920286
Epitope ID	4' BSC		ESCO LA2-4A2-E-PORT AF	2020-158844
Trans Sci	Black freezer/fridge combo	Kenmore		
Trans Sci	White freezer/fridge combo	kenmore		
Trans Sci	Arium advance	Sartorius	(needs new tank)	
Utility Room	LN2 distribution manifold	Concoa	5771113-01-100	20C16RPT
Utility Room	CO2 distribution manifold	Praxair	Prospec PRS9000	
Utility Room	Compressed air system with pressure vessel and air dryer	Atlas Copco	ZT 15	API796795
Utility Room	House vacuum system	Atlas Copco	GVS 300A	36940
Utility Room	Nitrogen charged pre-action fire suppression system	South-Tek Systems	Fireflex N2-Blast	
	Office workstations - approximately 151			
	Office chairs - approximately 465			
	Lab benches			
	Furniture in conference rooms - approximately 23			
	Whiteboards - approximately 67			
	TVs - approximately 30			
	Miscelanous office furniutre in soft seating and collaboration areas			
	Lab charis - approximately 160			
	Lab workstations/benches - approximately 260			
	All shades @ exterior perimeter windows			
	All shades @ exterior perimeter windows			
	Hoshizaki F-330BAH Ice flaker w/H9320-1 filter			
	Hoshizaki Modular Air-cooled Ice flaks			
	Ice Machine (Hoshizaki lab grade)			
	Freezer Ultra Low Temp	Stirling		
	All conference room AV equipment			
	Wireless Meraki Access Points - installed			
	Monitor arms and port replicators			
	Monitors attached to monitor arms			
	Polycoms in conf rooms			
CB Facs Core	micro-centrifuge	Eppendorf	Eppendorf, 5418	

ProtEng Yeast	Static non-CO2 incubator	VWR	89511-418 (Grav Conv 2.6 CF) Type Code: 51030015	42335717
ProtEng Downstream	iBind	Invitrogen		
ProtEng Downstream	iBindFlex	Invitrogen		
TM-MB ASSAY LAB	Digital Microscope Slide Scanner	Leica	Aperio AT2	7838



**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement No. 333-275556 on Form S-8 of our report dated March 21, 2024, relating to the financial statements of CARGO Therapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ Deloitte & Touche LLP

San Francisco, California

March 21, 2024

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**Certification of Chief Executive Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Gina Chapman, certify that:

1. I have reviewed this Annual Report on Form 10-K of CARGO Therapeutics, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
4. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
5. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. [Reserved];
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 21, 2024

/s/ Gina Chapman

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Gina Chapman

Chief Executive Officer

**(Principal Executive Officer)**

**Certification of Chief Financial Officer  
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Anup Radhakrishnan, certify that:

1. I have reviewed this Annual Report on Form 10-K of CARGO Therapeutics, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. [Reserved];
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 21, 2024

/s/Anup Radhakrishnan

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Anup Radhakrishnan

Chief Financial Officer

**(Principal Financial Officer)**

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Gina Chapman, Chief Executive Officer of CARGO Therapeutics, Inc. (the “Company”), and Anup Radhakrishnan, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 21, 2024

By: /s/ Gina Chapman  
Gina Chapman  
Chief Executive Officer  
**(Principal Executive Officer)**

Date: March 21, 2024

By: /s/ Anup Radhakrishnan  
Anup Radhakrishnan  
Chief Financial Officer  
**(Principal Financial Officer)**

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**CARGO THERAPEUTICS, INC. POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION**

Cargo Therapeutics, Inc. (the “*Company*”) has adopted this Policy for Recovery of Erroneously Awarded Compensation (the “*Policy*”), effective as of November 9, 2023 (the “*Effective Date*”). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

**1. Persons Subject to Policy**

This Policy shall apply to current and former Officers of the Company. Each Officer shall be required to sign an acknowledgment pursuant to which such Officer will agree to be bound by the terms of, and comply with, this Policy; however, any Officer’s failure to sign any such acknowledgment shall not negate the application of this Policy to the Officer.

**2. Compensation Subject to Policy**

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is “received” shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is “received” in the Company’s fiscal period during which the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

**3. Recovery of Compensation**

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person’s right to voluntarily terminate employment for “good reason,” or due to a “constructive termination” (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

**4. Manner of Recovery; Limitation on Duplicative Recovery**

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset

of the Erroneously Awarded Compensation against other compensation payable by the Company or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

#### **5. Administration**

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board of Directors of the Company (the “**Board**”) may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the “Committee” shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, equityholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

#### **6. Interpretation**

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

#### **7. No Indemnification; No Liability**

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person’s potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

## **8. Application; Enforceability**

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the “*Other Recovery Arrangements*”). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company or an affiliate of the Company.

## **9. Severability**

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

## **10. Amendment and Termination**

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

## **11. Definitions**

“*Applicable Rules*” means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company’s securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company’s securities are listed.

“*Committee*” means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

“*Erroneously Awarded Compensation*” means the amount of Incentive-Based Compensation received by a current or former Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.



“**Exchange Act**” means the Securities Exchange Act of 1934, as amended.

“**Financial Reporting Measure**” means any measure determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measures derived wholly or in part from such measures, including GAAP, IFRS and non-GAAP/IFRS financial measures, as well as stock or share price and total equityholder return.

“**GAAP**” means United States generally accepted accounting principles.

“**IFRS**” means international financial reporting standards as adopted by the International Accounting Standards Board.

“**Impracticable**” means (a) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company (i) has made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company’s home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

“**Incentive-Based Compensation**” means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Officer; (b) who served as an Officer at any time during the performance period for that compensation; (c) while the issuer has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

“**Officer**” means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

“**Restatement**” means an accounting restatement to correct the Company’s material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

“**Three-Year Period**” means, with respect to a Restatement, the three completed fiscal years immediately preceding the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes,

or reasonably should have concluded, that the Company is required to prepare such Restatement, or, if earlier, the date on which a court, regulator or other legally authorized body directs the Company to prepare such Restatement. The “Three-Year Period” also includes any transition period (that results from a change in the Company’s fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company’s previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.

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**ACKNOWLEDGMENT AND CONSENT TO  
POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION**

The undersigned has received a copy of the Policy for Recovery of Erroneously Awarded Compensation (the "***Policy***") adopted by Cargo Therapeutics, Inc. (the "***Company***").

For good and valuable consideration, the receipt of which is acknowledged, the undersigned agrees to the terms of the Policy and agrees that compensation received by the undersigned may be subject to reduction, cancellation, forfeiture and/or recoupment to the extent necessary to comply with the Policy, notwithstanding any other agreement to the contrary. The undersigned further acknowledges and agrees that the undersigned is not entitled to indemnification in connection with any enforcement of the Policy and expressly waives any rights to such indemnification under the Company's organizational documents or otherwise.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name

\_\_\_\_\_  
Title

