Filed pursuant to Rule 424(b)(4)
Registration No. 333-275113

18,750,000 shares

Common stock

This is an initial public offering of shares of common stock of CARGO Therapeutics, Inc. We are offering 18,750,000 shares of our common stock to be sold in this offering. The initial public offering price is $15.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock is listed on the Nasdaq Global Select Market under the symbol “CRGX.”

We are an “emerging growth company” and a “smaller reporting company” as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

	Per share	Total
Initial public offering price	$ 15.00	$281,250,000
Underwriting discounts and commissions(1)	$ 1.05	$ 19,687,500
Proceeds to CARGO Therapeutics, Inc. before expenses	$ 13.95	$261,562,500

(1) See the section titled “Underwriting” for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 2,812,500 shares of our common stock.

Investing in our common stock involves a high degree of risk. See the section titled “Risk factors” beginning on page 16.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about November 14, 2023.

J.P. Morgan **Jefferies** **TD Cowen** **Truist Securities**

November 9, 2023

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We have not, and the underwriters have not, authorized anyone to provide you any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. Neither we nor the underwriters take responsibility for, or provide any assurance as to the reliability of, any other information others may give you. This prospectus is an offer to sell only the shares offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or the possession or distribution of this prospectus or any free writing prospectus in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States. See the section titled “Underwriting.”

In this prospectus, “CARGO Therapeutics,” “CARGO,” the “company,” “we,” “us” and “our” refer to CARGO Therapeutics, Inc. and, where appropriate, our subsidiaries.

“CARGO,” the CARGO logos and other trade names, trademarks or service marks of CARGO appearing in this prospectus are the property of CARGO. Other trade names, trademarks or service marks appearing in this prospectus are the property of their respective holders. Solely for convenience, trade names, trademarks and service marks referred to in this prospectus appear without the ®, ™ and SM symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trade names, trademarks and service marks.

Through and including December 4, 2023 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Prospectus summary

This summary highlights information contained elsewhere in this prospectus. This summary may not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus carefully, including the sections titled "Risk factors," "Special note regarding forward-looking statements," "Management's discussion and analysis of financial condition and results of operations" and "Business," and our financial statements and related notes included elsewhere in this prospectus before making an investment decision. Unless the context requires otherwise, references in this prospectus to "we," "us," "our," "our company" and "CARGO" refer to CARGO Therapeutics, Inc.

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 from the National Cancer Institute (NCI), 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 and trafficking to tumor lesions, 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. 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 costimulation 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 CAR T-cell product candidate designed to address resistance mechanisms by targeting CD22, an alternate tumor antigen that is expressed in a vast majority of B-cell malignancies. We exclusively licensed the underlying autologously derived CAR for CRG-022 from the NCI. Prior to our licensing the underlying CAR from NCI, Stanford had begun a Phase 1 clinical trial of CRG-022 that is being conducted for research purposes, and which has enrolled 41 patients with R/R LBCL, 38 of whom received CRG-022. As of the most recent data cutoff date (May 3, 2023), the following results were reported:

- CR rate of 53% (20 of 38 patients);

- responses were durable with 85% of patients (17 of 20 patients) that achieved a CR maintained their response with a median follow up time of 23 months and a maximum of 43 months;
- only 3 of the 20 patients who achieved a CR have relapsed;
- overall response rate (ORR) of 68% (26 of 38 patients), which was statistically significant;
- median overall survival (OS) of 14.1 months;
- only 1 patient experienced Grade 3 or higher cytokine release syndrome (CRS), which happens when a patient's immune system responds to an infection or immunotherapy more aggressively than it should;
- 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. 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.

We understand that Stanford may pursue additional clinical trials of a similar CAR T 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 we anticipate Stanford will be 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 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. 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 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 and STASH platforms, 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 costimulation (e.g., 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 costimulatory domain into the tri-specific CAR T cell to counter a target-independent mechanism, the downregulation of CD58 (the ligand of the CD2 costimulatory 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 costimulation, which involves interaction of one or more costimulatory receptors on T cells, such as CD2, with their cognate ligands (a molecule that typically interacts with that 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 costimulatory 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 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 aberrant CD58 expression. We leveraged this platform to uniquely differentiate CRG-023.

Our second platform technology, which we refer to as STASH, is designed to enable multiplex engineering of a variety of immune cell types. This platform allows us to incorporate multiple transgene therapeutic "cargo" designed to enhance CAR T-cell persistence and trafficking to tumor lesions, as well as to help safeguard against tumor resistance and T-cell exhaustion. As is common among CAR T cell therapies, we use a virus, in the form of a lentiviral vector to deliver the genetic elements that modify the T cell. Engineering a multifunctional cell requires the introduction of additional genetic elements that often do not fit within a single lentiviral vector, requiring the use of multiple vectors. However, engineering cells with multiple vectors typically results in a heterogeneous cell product, and we are unaware of an efficient way to generate a homogenous CAR T-cell product using existing viral vector systems. Our STASH platform is designed to address this problem by employing a technology that selects only cells that possess all of the desired transgenes, which enables the production of a homogeneous population of CAR T cells produced using more than one delivery vector. We believe this technology will allow us to efficiently incorporate more genetic elements into our CAR T cells with the goal of enhancing the potential for efficacy, persistence and safety.

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 application 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. Notwithstanding the foregoing, 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. 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 solution: next generation of 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 limitations of currently approved products. Our solution includes:

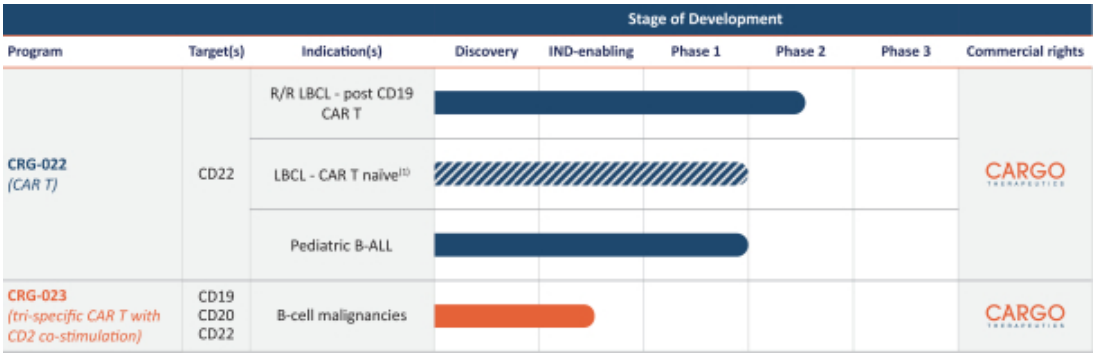
- ***Directing CAR T cells toward alternate targets***. Therapies that target single tumor antigens, such as CD19, can be rendered ineffective by genetic or non-genetic changes that diminish the expression of these targets. Our most advanced product candidate, CRG-022, is designed to address an alternate 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 therapies, starting with CRG-023, that can 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 costimulatory signaling, such as tumor cells downregulating CD58. Because these mechanisms are not antigen-specific, loss of costimulation can lead to broad suppression of immune therapies. We are addressing loss of costimulatory ligands such as CD58, by creating CAR T cells that can induce CD2 costimulatory signaling by a tumor antigen irrespective of potential CD58 downregulation or loss on tumor cells.
- ***Reducing anti-CAR immunogenicity due to species differences***. Our CAR T-cell product candidates are all constructed with human binders, thereby reducing the risk for anti-CAR immune responses.
- ***Addressing manufacturing challenges***. Our team is applying its extensive experience in the field 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

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 product candidates 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 intend to discuss with the FDA 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 costimulatory 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. 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. The median OS was 14.1 months. As of the May 3, 2023 cutoff date, 17 of 20 patients that achieved a CR maintained their response with a median follow up time of 23 months and a maximum of 43 months, which we believe suggests favorable durability. CRG-022 was generally well-tolerated with only one patient experiencing Grade 3 or higher CRS and no patients experiencing Grade 3 or higher ICANS. 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 have been actively engaged with the FDA in 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. We expect interim results from this Phase 2 clinical trial in 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 a tri-specific CAR designed to address tumor antigen loss and our CD2 platform technology to address loss of costimulatory 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 costimulatory domain into the tri-specific CAR T to counter a target-independent mechanism, the downregulation of CD58 (the ligand of the CD2 costimulatory 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 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 or eliminated CD58 expression. We leveraged this platform to uniquely differentiate our CRG-023 program. We are preparing to conduct IND-enabling studies with CRG-023.

Our history, team and investors

We were founded by pioneers and world experts in CAR T-cell therapy, and we have built a seasoned leadership team with experience and success developing, manufacturing, launching and commercializing oncology and cell therapy products.

Our founders include internationally recognized experts from Stanford and an acclaimed cancer advocate. Crystal Mackall, MD, Professor of Pediatrics and Internal Medicine at Stanford serves as Founding Director of the Stanford Center for Cancer Cell Therapy, Associate Director of Stanford Cancer Institute, Leader of the Cancer Immunology and Immunotherapy Program, and Director of the Parker Institute for Cancer Immunotherapy at Stanford. Dr. Mackall previously served as Chief of the Pediatric Oncology Branch at the NCI. Robbie Majzner, MD, is the Director of the Pediatric and Young Adult Cancer Cell Therapy Program within the Departments of Pediatric Oncology and Medical Oncology at Dana Farber Cancer Institute and the Division of Hematology/Oncology at Boston Children’s Hospital. Dr. Majzner’s laboratory is working to develop novel cellular immunotherapies for children with incurable cancers. Louai Labanieh, PhD is a Parker Scholar at Stanford School of Medicine and is a leader in engineering CAR T cells using synthetic biology. Nancy Goodman, JD, is the CEO of Kids v Cancer, a nonprofit organization dedicated to policy reform to attract biotech and pharmaceutical companies to pediatric cancer drug development.

Our management team has significant experience in both cell therapy and oncology. We have progressed products from research to clinical trials, and ultimately to regulatory approval and commercialization. Gina Chapman, our President and Chief Executive Officer, brings over 30 years of biopharmaceutical commercial and operational experience. She most recently served as Senior Vice President and Business Unit Head at

Genentech, where she worked for more than 15 years. Michael Ports, PhD, our Chief Scientific Officer, has over 10 years of biopharmaceutical and cell-therapy drug development experience. He most recently served as Vice President and Head of Cell Therapy Discovery and Platforms at Janssen. Shishir Gadam, PhD, our Chief Technical Officer, most recently was Vice President of Global Cell Therapy Manufacturing Science and Technology at Bristol Myers Squibb (BMS). He played an instrumental role in the global licensure and launch of the CAR T-cell products Breyanzi and Abecma and built a global manufacturing science and technology organization responsible for product and process life-cycle management, technology transfers and manufacturing technology. Anup Radhakrishnan, our Chief Financial Officer and Chief Business Officer, brings over 20 years of experience in the biopharmaceutical sector providing strategic financial leadership across both clinical and commercial stage organizations. He previously served as CFO at Dascena and worked at Genentech for over 11 years. 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. As a result, we believe having a management team with significant relevant experience positions us well to overcome these challenges.

We are also supported by our board of directors, scientific advisory board and a leading syndicate of investors.

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.***
- ***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.***
- ***Expand development of CRG-022 to earlier lines of therapy and additional indications.***
- ***Leverage our intended commercial and readily transferable manufacturing process to help mitigate regulatory hurdles and facilitate predictable and reliable supply for future patients.***
- ***Continue to leverage our platform technologies to advance additional CAR T-cell programs into clinical development.***
- ***Opportunistically pursue strategic partnerships and collaborations to maximize the value of our pipeline and platform technologies.***

Certain Preliminary Financial Information (Unaudited)

As of September 30, 2023, we had approximately $60.3 million in cash and cash equivalents. This estimate of our cash and cash equivalents is preliminary and subject to completion, including the completion of interim review procedures as of and for the nine months ended September 30, 2023. As a result, the unaudited preliminary cash and cash equivalents set forth above reflects our preliminary estimate with respect to such information, based on information currently available to management, and may vary from our actual financial position as of September 30, 2023. Further, this preliminary estimate is not a comprehensive statement or estimate of our financial results or financial condition as of and for the nine months ended September 30, 2023. The unaudited preliminary cash and cash equivalents included herein has been prepared by, and is the

responsibility of, management. Our independent registered public accounting firm has not audited, reviewed, compiled or performed any procedures with respect to the unaudited preliminary cash and cash equivalents and, accordingly, our independent registered public accounting firm does not express an opinion or any other form of assurance with respect thereto. It is possible that we or our independent registered public accounting firm may identify items that require us to make adjustments to the financial information set forth above. This estimate should not be viewed as a substitute for financial statements prepared in accordance with accounting principles generally accepted in the United States and they are not necessarily indicative of the results to be achieved in any future period. Accordingly, you should not draw any conclusions based on the foregoing estimate and should not place undue reliance on this preliminary estimate. We assume no duty to update this preliminary estimate except as required by law.

Risk factors 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 prospectus 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.
- Even if this offering is successful, 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.
- 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 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.

Before you invest in our common stock, you should carefully consider all of the information in this prospectus, including matters set forth in the section titled “Risk factors.”

Corporate information

We were founded in December 2019 as a Delaware corporation under the name Syncopation Life Sciences, Inc. We changed our name to CARGO Therapeutics, Inc. in September 2022. Our principal executive offices are located at 1900 Alameda De Las Pulgas, Suite 350, San Mateo, California 94403, and our telephone number is (650) 379-6143.

Our website address is www.cargo-tx.com. The information on, or that can be accessed through, our website is not part of this prospectus and is not incorporated by reference herein. We have included our website address as an inactive textual reference only.

Implications of being an emerging growth company and a smaller reporting company

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we will present in this prospectus only two years of audited annual financial statements, plus any required unaudited interim condensed financial statements, and related management’s discussion and analysis of financial condition and results of operations;
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our independent registered public accounting firm on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require non-binding, advisory stockholder votes on executive compensation or golden parachute arrangements.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company; however, we have and may adopt certain new or revised accounting standards early.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.

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 may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as 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.

The offering

Common stock offered by us	18,750,000 shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to 2,812,500 additional shares of common stock from us at any time within 30 days from the date of this prospectus.
Common stock to be outstanding immediately after this offering	38,672,544 shares (or 41,485,044 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $256.3 million (or approximately $295.5 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund the planned Phase 2 clinical trials of CRG-022, to fund our internal research and development capabilities to advance new product candidates, and the remainder for working capital and other general corporate purposes, including the additional costs associated with being a public company. We may also use a portion of the net proceeds to in-license, acquire, or invest in, complementary technologies, assets, or intellectual property. We regularly evaluate strategic opportunities; however, we have no current commitments to enter into any such license arrangements or acquisition agreements or to make any such investments. See the section titled “Use of Proceeds.”
Risk factors	See the section titled “Risk Factors” and other information included in this prospectus for a discussion of factors you should carefully consider before deciding whether to invest in our common stock.
Nasdaq Global Select Market trading symbol	“CRGX”

Unless we specifically state otherwise or the context otherwise requires, the number of shares of our common stock to be outstanding after this offering is based on 19,922,544 shares of common stock outstanding as of June 30, 2023 (after giving effect to the automatic conversion of (1) all of our shares of our convertible preferred stock outstanding as of June 30, 2023 and (2) the 3,381,941 and 6,341,148 shares of our Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche

closing in October 2023, respectively, into an aggregate of 18,836,559 shares of our common stock immediately prior to the completion of this offering) and excludes:

- 2,147,565 shares of our common stock issuable upon the exercise of stock options outstanding under our 2021 Stock Option and Grant Plan (the 2021 Plan) as of June 30, 2023, with a weighted-average exercise price of $4.73 per share;
- 1,550,776 shares of our common stock issuable upon the exercise of stock options granted under the 2021 Plan subsequent to June 30, 2023, with a weighted-average exercise price of $9.50 per share;
- 502,192 shares of our common stock reserved for future issuance under the 2021 Plan as of June 30, 2023, which shares ceased to be available for issuance at the time our 2023 Incentive Award Plan (the 2023 Plan) became effective;
- a number of shares of our common stock equal to 10% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) reserved for future issuance under the 2023 Plan, which became effective on the date immediately prior to the date our registration statement relating to this offering became effective, as well as any future increases in the number of shares of common stock reserved for issuance under the 2023 Plan; and
- a number of shares of our common stock equal to 1% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) reserved for future issuance under our Employee Stock Purchase Plan (the ESPP), which became effective on the date immediately prior to the date our registration statement relating to this offering became effective, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

Unless we specifically state otherwise or the context otherwise requires, this prospectus reflects and assumes the following:

- the adoption, filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the completion of this offering;
- the automatic conversion of (1) all outstanding shares of our convertible preferred stock outstanding as of June 30, 2023 and (2) the 3,381,941 and 6,341,148 shares of our Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche closing in October 2023, respectively, into an aggregate of 18,836,559 shares of our common stock immediately prior to the completion of this offering;
- no exercise, settlement or termination of the outstanding stock options described above;
- a 13.5685-for-1 stock split of our capital stock, which we effected on November 3, 2023; and
- no exercise by the underwriters of their option to purchase up to 2,812,500 additional shares of our common stock in this offering.

Summary financial data

The following tables summarize our historical financial data for the periods and as of the dates indicated. We have derived the summary statements of operations and comprehensive loss data for the years ended December 31, 2021 and 2022, except for pro forma amounts, from our audited financial statements and related notes included elsewhere in this prospectus. We have derived the summary statements of operations and comprehensive loss data for the six months ended June 30, 2022 and 2023, except for pro forma amounts, and the summary balance sheet data as of June 30, 2023, except for pro forma and pro forma as adjusted amounts, from our unaudited interim condensed financial statements and related notes as of and for the six months ended June 30, 2022 and 2023 included elsewhere in this prospectus. Our unaudited interim condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in our opinion, all adjustments of a normal and recurring nature that are necessary for the fair statement of the financial information set forth in those statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of results that may be expected in the future and our interim results are not necessarily indicative of results that may be expected for the full year. You should read the following summary financial data together with our audited financial statements, unaudited interim condensed financial statements and related notes included elsewhere in this prospectus and the information in the section titled “Management’s discussion and analysis of financial condition and results of operations.”

(in thousands, except per share and per share data)	Year ended December 31, 2021	Year ended December 31, 2022	Six months ended June 30, 2022	Six months ended June 30, 2023
			(unaudited)	
Statements of operations and comprehensive loss data:				
Operating expenses:				
Research and development	$ 4,461	$ 29,373	$ 11,673	$ 26,491
General and administrative	1,516	5,398	2,044	6,552
Total operating expenses	5,977	34,771	13,717	33,043
Loss from operations	(5,977)	(34,771)	(13,717)	(33,043)
Interest expense	—	(4,942)	(776)	(1,604)
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	—	—	(692)
Change in fair value of derivative liabilities	—	(1,216)	(407)	6,453
Loss on extinguishment of convertible notes	—	—	—	(2,316)
Other income (expense), net	127	(22)	(17)	603
Net loss and comprehensive loss	$ (5,850)	$ (40,951)	$ (14,917)	$ (30,599)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (38.38)	$ (104.40)	$ (50.01)	$ (48.21)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted[1]	152,422	392,268	298,296	634,704
Pro forma net loss per share of common stock, basic and diluted (unaudited)[2]		$ (1.81)		$ (1.67)
Pro forma weighted-average shares of common stock outstanding, basic and diluted (unaudited)[2]		19,228,827		19,471,265

(1) See Note 14 to our audited financial statements and Note 12 to our unaudited interim condensed financial statements included elsewhere in this prospectus for details on the calculations of historical basic and diluted net loss per share and the weighted-average number of shares attributable to common stockholders used in computation of these per share amounts.

(2) The unaudited pro forma basic and diluted net loss per share for the year ended December 31, 2022 and for the six months ended June 30, 2023 have been prepared to give effect to the assumed conversion of outstanding shares of convertible preferred stock to common stock at December 31, 2022 and June 30, 2023, respectively, as if the convertible preferred stock was outstanding as of January 1, 2022 or January 1, 2023, respectively, irrespective of when the convertible preferred stock was issued.

(in thousands)	June 30, 2023		
	Actual	Pro forma[1]	Pro forma as adjusted[2]
		(unaudited)	
Balance sheet data:			
Cash and cash equivalents	$ 42,371	$ 174,299	$ 430,562
Working capital[3]	18,631	158,568	415,049
Total assets	60,497	190,409	446,454
Convertible preferred stock	106,166	—	—
Additional paid-in capital	2,618	248,702	504,946
Accumulated deficit	(77,598)	(77,598)	(77,598)
Total stockholders' (deficit) equity	(74,979)	171,124	427,387

(1) The pro forma balance sheet data gives effect to the (i) automatic conversion of all of our outstanding shares of our convertible preferred stock into an aggregate of 18,836,559 shares of our common stock (including 3,381,941 and 6,341,148 shares of Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche closing in October 2023, respectively), and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the completion of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering.

(2) The pro forma as adjusted column in the balance sheet data table above gives effect to (i) the pro forma adjustments described in footnote (1) above and (ii) the sale and issuance of 18,750,000 shares of common stock by us in this offering at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities. See our audited financial statements and unaudited interim condensed financial statements and related notes thereto included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

Risk factors

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this prospectus, including the section titled "Management's discussion and analysis of financial condition and results of operations" and our audited financial statements and unaudited interim condensed financial statements and related notes included elsewhere in this prospectus, before making an investment decision. 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.

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 and convertible promissory notes 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 $41.0 million for the year ended December 31, 2022 and $30.6 million for the six months ended June 30, 2023. As of June 30, 2023, we had an accumulated deficit of $77.6 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 and STASH platforms, 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 GMP 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.

Even if this offering is successful, 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 (NCI) and Oxford BioMedica (UK) Limited (Oxford). 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. 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, upon the completion of this offering, we expect to incur additional costs associated with operating 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.

As of June 30, 2023, we had $42.4 million of cash and cash equivalents. Without giving effect to the anticipated net proceeds from this offering, based on our current operating plan we expect that our existing cash and cash equivalents will not be sufficient to fund our planned operating expenses and capital expenditures beyond one year from the issuance date of our financial statements. We believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through 2025.

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 and STASH platforms;
- 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 the COVID-19 pandemic;
- 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, the net proceeds from this offering, 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.

There is substantial doubt about our ability to continue as a going concern.

We have prepared cash flow forecasts which indicate that, based on our expected operating losses and negative cash flows, there is substantial doubt about our ability to continue as a going concern for the twelve months after the respective dates our financial statements for the year ended December 31, 2022 and the six months ended June 30, 2023 were issued. As a result, management has included disclosures in Note 1 of the financial statements and our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements for the fiscal year ended December 31, 2022 with respect to this uncertainty. Our future viability as an ongoing business is dependent on our ability to generate cash from our operating activities and to raise additional capital to finance our operations.

There is no assurance that we will succeed in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to

us, or at all, and could result in the loss of confidence by investors and employees. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our investors will lose all or a part of their investment.

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 (UK) Limited (Oxford Agreement) 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 agreement with the NCI, pursuant to which we obtained a worldwide, royalty-bearing, exclusive license 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 in milestone payments upon achievement of specific intellectual property, clinical and commercial milestone events and low single-digit percentage royalties on net sales of products incorporating the licensed patent rights from the NCI. Additionally, 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 “Management’s discussion and analysis of financial condition and results of operations—License agreements” elsewhere in this prospectus 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 as part of the potentially pivotal Phase 2 clinical trial;
- 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 June 30, 2023, we had grown to 74 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 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 current Good Manufacturing Practice (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.

We may be unable to secure permission to use data from the previous clinical trials conducted by certain of our license agreement counterparties.

We are pursuing entering into agreements with certain of our license agreement counterparties whereby we would be able to use clinical data such counterparties had already generated from clinical trials or preclinical studies. We would utilize this data, if procured, as part of the approval process for our product candidates and for other purposes. If we are unable to secure such agreements at a reasonable price, or at all, we may not be able to pool the data with data generated from our clinical trials, utilize such data for demonstrating durability and safety or otherwise leverage the data to support our regulatory filings. If we cannot utilize the data for the aforementioned purposes, 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 prospectus 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 included in this prospectus 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 percent 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 commenced clinical trials or 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 and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we 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, we cannot assure that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. 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 computer 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 or proprietary information or patient information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

Furthermore, significant disruptions of our internal information technology systems or those of our third-party service providers, or security breaches could result in the loss, corruption, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to actual or suspected, or is alleged to lead to, unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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, content delivery to customers 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 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 data 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 data 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 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information. The California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA), (collectively, CCPA) applies to personal information of consumers, business representatives and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for administrative fines of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, the CPRA expanded the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the law. Other states, such as Virginia and Colorado, 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 states, like the CCPA, 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 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

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, and the EU-U.S. Data Privacy Framework (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, 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 disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. 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 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 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 be a remain a focus for such regulatory authorities during their reviews of our applications. Moreover, even if we commence 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 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 CMO delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs 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 on 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.

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 tested our product candidates in clinical trials and any favorable data from trials conducted by Stanford University or NCI may not be replicated in our clinical trials.

We have not successfully tested 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. 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 the outcome in our Phase 2 clinical trial will be consistent with the outcome observed in the Stanford University conducted Phase 1 clinical trial.

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 clearance 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 nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical 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, 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 device 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.

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 1 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 of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates, and any resurgence of COVID-19 or emergence of new variants may lead to further inspectional delays. If a prolonged government shutdown occurs, or if global health concerns continue to 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 thereunder.

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 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 establishes 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.

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 eliminates the statutory cap on the Medicaid drug rebate, currently set at 100% of a drug's AMP, beginning January 1, 2024. 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 recently, the Inflation Reduction Act of 2022 (IRA), included a number of significant drug pricing reforms, which include the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services (HHS) (beginning in 2023) that requires manufacturers to negotiate with HHS and (beginning in 2026) charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation (first due in 2023), and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs (beginning in 2025). The IRA permits the HHS Secretary 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 guidance 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. However, the Medicare drug

price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but it is likely to have a significant effect on the pharmaceutical industry. Additional drug pricing proposals could appear in future legislation. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or 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;

- the federal Health Insurance Portability and Accountability Act of 1996 (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 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 our 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, 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 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.

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

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

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

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 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 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 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 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 this offering and ownership of our common stock

Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

The trading price of our common stock may 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 initial public offering price. 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 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 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 shortages;
- 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 after this offering 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 quarterly 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 quarterly 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 candidate 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 quarterly 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 quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly 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 improve our internal control over financial reporting, including the hiring of qualified supervisory resources, the engagement of technical accounting consulting resources and plans to hire additional finance department employees.

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.

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.

Prior to this offering, as of June 30, 2023, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates owned approximately 48.5% of our outstanding voting stock and, upon the closing of this offering, that same group will own approximately 27.3% of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares). Therefore, even after this offering, 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. In addition, certain of our principal stockholders, including Samsara, Perceptive, Third Rock Ventures and Red Tree Venture, have designated certain of our directors for election to the Board. 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.

Future sales of our common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock after this offering 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.

Upon the completion of this offering, 38,672,544 shares of common stock will be outstanding (41,485,044 shares if the underwriters exercise their option to purchase additional shares from us in full), based on the number of shares outstanding as of June 30, 2023.

All shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless held by our “affiliates” as defined in Rule 144 under the Securities Act. The resale of the remaining 19,922,544 shares, or 51.5% of our outstanding shares of common stock following this offering, is currently prohibited or otherwise restricted, subject to certain limited exceptions, as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on the 181st day after the date of this prospectus. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see the section titled “Shares eligible for future sale.”

Upon the completion of this offering, the holders of approximately 18,910,251 shares, or 48.9% of our outstanding shares following this offering, of our common stock will 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. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements described under “Underwriting.”

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.

Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the net proceeds from this offering in ways with which investors disagree.

Our management will have broad discretion over the use of net proceeds from this offering, and could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the net proceeds from this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline. For additional details see the section titled “Use of proceeds.”

If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our outstanding common stock immediately following the completion of this offering. If you purchase shares of common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share of $3.95 per share as of June 30, 2023, at the initial public offering price of $15.00 per share. That is because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution when those holding stock options exercise their right to purchase common stock under our equity incentive plans or when we otherwise issue additional shares of common stock. For additional details see the section titled “Dilution.”

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 for 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, each to be in effect immediately prior to the completion of this offering, will 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 will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders 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 to be in effect upon the completion of this offering will provide 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 will provide 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, 2022, we had U.S. federal and state net operating loss carryforwards (NOLs) of $5.9 million and $2.3 million, respectively. Our federal NOL carryforwards of $5.9 million carry forward indefinitely. The state NOL carryforwards of $2.3 million begin to expire in 2040. In addition, as of December 31, 2022, we have U.S. federal and state research and development tax credits of $1.8 million and $1.7 million, respectively. The federal research and development tax credits of $1.8 million begin to expire in 2042. The state research and development tax credits of $1.7 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 as a result of this offering 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, 2022, 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.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

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 will be 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.

There has been no prior public market for our common stock, and an active trading market may not develop or be sustained.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock was determined through negotiations among the underwriters and us and may vary from the trading price of our common stock following this offering. An active or liquid market in our common stock may not develop upon closing of this offering or, if it does develop, it may not be sustainable. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. 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.

We are an emerging growth company and a smaller reporting company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

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 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 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 will be 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 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 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 prospectus and in future filings required of a public company, 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.

After this offering, we will be subject to Section 404 and the related rules of the SEC, which, subject to certain exceptions, generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. In addition, once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex, judgmental and

require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to 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.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design 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.

Special note regarding forward-looking statements

This prospectus contains forward-looking statements, particularly in the sections titled “Prospectus summary,” “Risk factors,” “Management’s discussion and analysis of financial condition and results of operations” and “Business.” In some cases, you can identify these statements by forward-looking words such as “aim,” “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “should,” “would” or “will,” the negative of these terms and other comparable terminology. These forward-looking statements, which are subject to risks, 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 IND submissions to the FDA 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 nonclinical 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 REMs;
- 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 Exchange Act;
- developments and projections relating to our competitors and our industry, including competing products;
- our expectations regarding the use of proceeds from this offering and our existing cash and cash equivalents; and
- other risks and uncertainties, including those listed under the caption “Risk factors” in this prospectus.

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 prospectus, 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. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Industry and market data

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size, is based on information from various sources, on assumptions that we have made based on such information and other, similar sources and on our knowledge of, and expectations about, the markets for our products. In some cases, we do not expressly refer to the sources from which this data is derived. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including but not limited to those described in the section titled “Risk factors” and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by independent third parties and by us.

Use of proceeds

We estimate that the net proceeds from this offering will be approximately $256.3 million (or approximately $295.5 million if the underwriters exercise their option to purchase additional shares in full) based on the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $220.0 million to fund the planned Phase 2 clinical trials of CRG-022;
- approximately $20.0 million to fund our internal research and development capabilities to advance new product candidates; and
- the remainder for working capital and other general corporate purposes, including the additional costs associated with being a public company.

We may also use a portion of the net proceeds to in-license, acquire or invest in complementary technologies, assets or intellectual property. We regularly evaluate strategic opportunities; however, we have no current commitments to enter into any such license arrangements or acquisition agreements or to make any such investments.

Based on our current operating plan, we believe that our existing cash and cash equivalents, together with the estimated net proceeds from this offering, will be sufficient to meet our working capital and capital expenditure needs through 2025. Our expected use of net proceeds from this offering represents our current intentions based upon present plans and business conditions.

The net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient to fund any of our product candidates through regulatory approval, and we anticipate needing to raise additional capital to complete the development of and commercialize our product candidates. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of any expenditures will vary depending on numerous factors, including the progress of our ongoing and planned clinical studies, the amount of cash used by our operations, competitive, scientific and data science developments, the rate of growth, if any, of our business, and other factors described in the section titled “Risk factors.” Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of these net proceeds. Due to the many inherent uncertainties in the development of our product candidates, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, our ability to obtain additional financing, the cost and results of our preclinical activities, the timing of clinical studies we may commence in the future, the timing of regulatory submissions, any collaborations that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs.

Pending the uses described above, we intend to invest the net proceeds from this offering in interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Dividend policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. We currently anticipate that we will retain all available funds for use in the operation and expansion of our business. Any future determination as to the declaration or payment of dividends on our common stock will be made at the discretion of our board of directors and will depend upon, among other factors, our financial condition, results from operations, current and anticipated cash needs, plans for expansion and other factors that our board of directors may deem relevant.

Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of June 30, 2023:

- on an actual basis;
- on a pro forma basis to reflect the following immediately prior to the completion of this offering: (i) the automatic conversion of all of our outstanding shares of our convertible preferred stock into an aggregate of 18,836,559 shares of our common stock (including 3,381,941 and 6,341,148 shares of Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche closing in October 2023, respectively), and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the completion of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect: (i) the pro forma adjustments set forth above and (ii) the sale and issuance of 18,750,000 shares of common stock by us in this offering at the initial public offering price of $15.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

This table should be read in conjunction with the section titled “Management’s discussion and analysis of financial condition and results of operations” and our unaudited interim condensed financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2023		
(in thousands, except share and per share data)	**Actual**	**Pro forma**	**Pro forma as adjusted**
		(unaudited)	
Cash and cash equivalents	$ 42,371	$ 174,299	$ 430,562
Redeemable convertible preferred stock, $0.001 par value per share; 255,584,255 shares authorized, 9,113,470 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	$106,166	$ —	$ —
Stockholders’ deficit:			
Preferred stock, $0.001 par value per share; no shares authorized, issued or outstanding, actual; 50,000,000 shares authorized, no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, $0.001 par value per share; 320,000,000 shares authorized, 1,085,985 shares issued and outstanding, actual; 500,000,000 shares authorized and 19,922,544 shares issued and outstanding, pro forma; 500,000,000 shares authorized and 38,672,544 shares issued and outstanding, pro forma as adjusted	1	20	39
Additional paid-in capital	2,618	248,702	504,946
Accumulated deficit	(77,598)	(77,598)	(77,598)
Total stockholders’ (deficit) equity	(74,979)	171,124	427,387
Total capitalization	$ 31,187	$ 171,124	$ 427,387

The number of shares of our common stock to be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 19,922,544 shares of common stock outstanding as of June 30, 2023 (after giving effect to the automatic conversion of (1) all of our shares of our convertible preferred stock outstanding as of June 30, 2023 and (2) the 3,381,941 and 6,341,148 shares of our Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche closing in October 2023, respectively, into an aggregate of 18,836,559 shares of our common stock immediately prior to the completion of this offering), and excludes:

- 2,147,565 shares of our common stock issuable upon the exercise of stock options outstanding under the 2021 Plan as of June 30, 2023, with a weighted-average exercise price of $4.73 per share;
- 1,550,776 shares of our common stock issuable upon the exercise of stock options granted under the 2021 Plan subsequent to June 30, 2023, with a weighted-average exercise price of $9.50 per share;
- 502,192 shares of our common stock reserved for future issuance under the 2021 Plan as of June 30, 2023, which shares ceased to be available for issuance at the time the 2023 Plan became effective;
- a number of shares of our common stock equal to 10% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) reserved for future issuance under the 2023 Plan, which became effective on the date immediately prior to the date our registration statement relating to this offering became effective, as well as any future increases in the number of shares of common stock reserved for issuance under the 2023 Plan; and
- a number of shares of our common stock equal to 1% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) reserved for future issuance under the ESPP, which became effective on the date immediately prior to the date our registration statement relating to this offering became effective, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

Dilution

If you purchase shares of our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of June 30, 2023, we had a historical net tangible book value (deficit) of $(75.2) million, or $(69.24) per share of common stock, based on 1,085,985 shares of our common stock issued and outstanding as of such date. Our historical net tangible book value (deficit) represents our total tangible assets excluding deferred offering costs, less our total liabilities and convertible preferred stock, which is not included within stockholders' equity (deficit), divided by the total number of shares of our common stock outstanding as of June 30, 2023.

Our pro forma net tangible book value as of June 30, 2023, was $170.9 million, or $8.58 per share. Pro forma net tangible book value represents our total tangible assets excluding deferred offering costs, less our total liabilities, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of June 30, 2023 into an aggregate of 18,836,559 shares of our common stock (including 3,381,941 and 6,341,148 shares of Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche closing in October 2023, respectively), and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the completion of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares of common stock outstanding as of June 30, 2023, after giving effect to the conversion of our convertible preferred stock.

After giving further effect to the sale and issuance by us of the 18,750,000 shares of our common stock in this offering at the initial public offering price of $15.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2023 would be $427.4 million, or $11.05 per share. This represents an immediate increase in pro forma net tangible book value to our existing stockholders of $2.47 per share and an immediate dilution to new investors of $3.95 per share. Dilution per share to new investors represents the difference between the price per share to be paid by new investors for the shares of common stock sold in this offering and the pro forma as adjusted net tangible book value per share immediately after this offering.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$15.00
Historical net tangible book value (deficit) per share as of June 30, 2023	$(69.24)	
Pro forma increase in historical net tangible book value (deficit) per share as of June 30, 2023 attributable to the pro forma adjustments described above	77.82	
Pro forma net tangible book value per share as of June 30, 2023	8.58	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	2.47	
Pro forma as adjusted net tangible book value per share after this offering		11.05
Dilution per share to new investors participating in this offering		$ 3.95

If the underwriters' option to purchase additional shares is exercised in full, the pro forma as adjusted net tangible book value per share of our common stock would be $11.25 per share, and the dilution in pro forma net tangible book value per share to new investors in this offering would be $3.75 per share, based on the initial public offering price of $15.00 per share.

The following table summarizes, as of June 30, 2023, on a pro forma as adjusted basis, the number of shares of common stock purchased from us, the total consideration paid, or to be paid, and the weighted-average price per share paid, or to be paid, by existing stockholders and by the new investors, at the initial public offering price of $15.00 per share before deducting underwriting discounts and commissions and offering expenses payable by us:

	Shares purchased		Total consideration		Weighted-average price per share
(in thousands, except share, per share and percent data)	Number	Percent	Amount	Percent	
Existing stockholders	19,922,544	51.5%	$ 244,007	46.5%	$ 12.25
New investors	18,750,000	48.5%	281,250	53.5%	$ 15.00
Total	38,672,544	100.0%	$ 525,257	100.0%	

The above table assumes no exercise of the underwriters' option to purchase additional shares. If the underwriters' option to purchase additional shares were exercised in full, our existing stockholders would own 48.0% and our new investors would own 52.0% of the total number of shares of our common stock outstanding upon completion of this offering.

To the extent that stock options are exercised, new stock options are issued under our equity incentive plan or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The foregoing tables and calculations (other than historical net tangible book value) are based on 19,922,544 shares of common stock outstanding as of June 30, 2023 (after giving effect to the automatic conversion of (1) all of our shares of convertible preferred stock outstanding as of June 30, 2023 and (2) the 3,381,941 and 6,341,148 shares of our Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche closing in October 2023, respectively, into an aggregate of 18,836,559 shares of our common stock immediately prior to the completion of this offering), and excludes:

- 2,147,565 shares of our common stock issuable upon the exercise of stock options outstanding under the 2021 Plan as of June 30, 2023, with a weighted-average exercise price of $4.73 per share;
- 1,550,776 shares of our common stock issuable upon the exercise of stock options granted under the 2021 Plan subsequent to June 30, 2023, with a weighted-average exercise price of $9.50 per share;
- 502,192 shares of our common stock reserved for future issuance under the 2021 Plan as of June 30, 2023, which shares ceased to be available for issuance at the time the 2023 Plan became effective;
- a number of shares of our common stock equal to 10% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) reserved for future issuance under the 2023 Plan, which became effective on the date immediately prior to the date our registration statement relating to this offering became effective, as well as any future increases in the number of shares of common stock reserved for issuance under the 2023 Plan; and

- a number of shares of our common stock equal to 1% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) reserved for future issuance under the ESPP, which became effective on the date immediately prior to the date our registration statement relating to this offering became effective, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

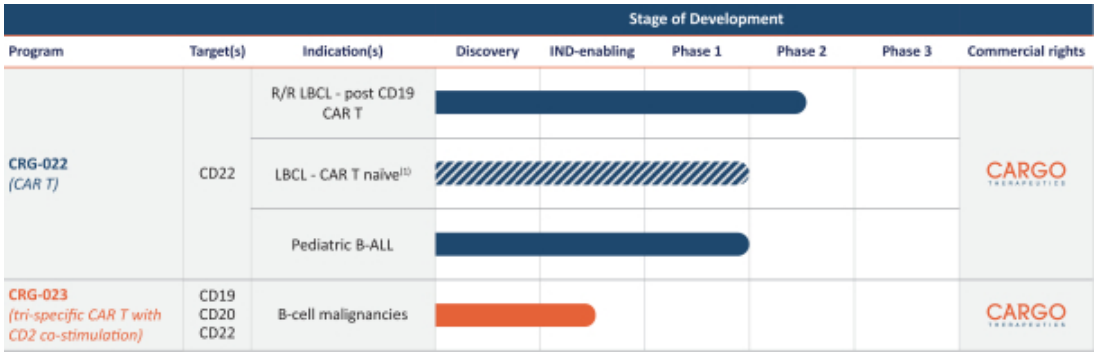
To the extent any outstanding options or other rights are exercised, or we issue additional equity or convertible securities in the future, there will be further dilution to new investors.

Management's discussion and analysis of financial condition and results of operations

You should read the following discussion of our financial condition and results of operations in conjunction with the section titled "Prospectus summary—Summary financial data" and our historical audited financial statements and our unaudited interim condensed financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this prospectus, particularly in the section titled "Risk Factors."

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 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 and trafficking to tumor lesions, 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.



(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 intend to discuss with the FDA initiation of a Phase 2 program in LBCL – CAR T nalve without completing earlier clinical trials in LBCL – CAR T-nave patients.

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 $14.9 million and $30.6 million for the six months ended June 30, 2022 and 2023, respectively, and $5.9 million and $41.0 million for the years ended December 31, 2021 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $77.6 million and cash and cash equivalents of $42.4 million. During the six months ended June 30, 2023, we issued convertible notes for an aggregate principal amount of $3.5 million and 5,072,919 shares of our Series A-1 redeemable convertible preferred stock for net proceeds of $68.1 million. In July and October 2023, we completed the second and third tranche closings of our Series A financing and issued 3,381,941 and 6,341,148 shares of Series A-1 redeemable convertible preferred stock for gross proceeds of $45.9 million and $86.0 million, respectively. Based on our current operating plans, we estimate that our existing cash and cash equivalents, together with the estimated net proceeds from this offering, 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. 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.

We utilize third-party contract manufacturing organizations (CMOs), to manufacture and supply our preclinical and clinical materials during the development of our product candidates. 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 CMOs are defined in the respective manufacturing and supply agreements.

License agreements

The following is a summary of certain of the key terms of our license agreements. For additional details, see the section titled “Business—License agreements.”

Stanford license agreement

In August 2022, we entered into an exclusive license agreement with Stanford University pursuant to which Stanford University granted us the right to make, use and sell products covered by the licensed patent rights for CD-2 platform technology (Stanford License Agreement). The technology licensed under this agreement may be used in a future product candidate currently under development and is not used in our lead program, CRG-022.

As consideration for the license granted under the Stanford License Agreement, we incurred a one-time, non-refundable upfront 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. In addition to annual license maintenance fees of up to $0.1 million per year, we may be required to pay up to $12.0 million in milestone payments upon achievement of specific intellectual property, clinical, regulatory and commercial milestones, and to pay earned royalties at a low single-digit percentage on net sales of a therapeutic product, subject to an anti-stacking provision. We are also obligated to pay Stanford a percentage of non-royalty revenue received from sub-licenses in the event we exercise our right to sublicense under the Stanford License Agreement.

Oxford license and supply agreement

In June 2022, we entered into a License and Supply Agreement (Oxford Agreement), with Oxford for the manufacture and supply of lentiviral vectors for clinical and potentially commercial purposes. Under the Oxford

Agreement, Oxford granted us a non-exclusive worldwide, royalty-bearing license under certain intellectual property rights for the purposes of research, development and commercialization of products transduced with the vectors.

As consideration for the license granted under the Oxford Agreement, we incurred an upfront fee of $0.2 million, and may be required to pay if certain development, regulatory and commercial milestones are achieved. Additionally, we are obligated to pay an earned royalty on net sales of products manufactured with the Oxford vector at a low single digit percentage.

National Cancer Institute

In March 2022, we entered into an exclusive license agreement (2022 NCI License Agreement) with the U.S. Department of Health and Human Services, as represented by The National Cancer Institute (NCI), pursuant to which we obtained an exclusive, worldwide, royalty-bearing license under certain patent rights to research, develop and commercialize products related to our CRG-022 program covered by such licensed patents.

We are required to pay NCI a non-refundable license fee of $0.6 million, of which $0.2 million was paid in 2022, and the remaining balance of $0.4 million is payable in three equal annual installments, beginning on the first anniversary of the effective date of the agreement. We accrued these non-refundable upfront fees on entering into the 2022 NCI License Agreement. We may be required to pay up to $18.0 million in milestone payments upon achievement of specific clinical and commercial milestones and an earned royalty on net sales of autologous cell therapy products covered by the licensed patent rights at a low single-digit percentage, depending on the amount of annual net sales. We are 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. We are obligated to pay the NCI a percentage (ranging from 5-10% on the low-end of the range to 15-25% on the high-end of the range) of non-royalty revenue in the event we choose to exercise our right to sublicense. Additionally, in the event we are granted a priority review voucher (PRV), we would be obligated to pay 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 Food and Drug Administration (FDA). We are also obligated to pay NCI a percentage (ranging from 2-7% on the low-end of the range to 7-12% on the high-end of the range) of the fair market value of the consideration we receive for any assignment of the 2022 NCI License Agreement to a non-affiliate (upon NCI's prior written consent) or an allocated portion of the fair value of consideration received in connection with a change in control.

In February 2023, we entered into another exclusive license agreement (2023 NCI License Agreement) with NCI pursuant to which we obtained an exclusive, worldwide, royalty-bearing license under certain patent rights to research, develop and commercialize products related to our CRG-022 program covered by such licensed patents.

We are required to pay NCI a non-refundable license fee of $0.3 million in three annual installments. Additionally, we must reimburse NCI for $0.1 million in expenses incurred by 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 Agreement. We accrued these non-refundable upfront fees and patent reimbursement expenses upon entering into the 2023 NCI License Agreement on the balance sheet. We may be required to pay up to $17.8 million in milestone payments upon achievement of specific clinical and commercial milestones and low single-digit percentage royalties on net sales of products incorporating the licensed patent rights. The 2023 NCI License Agreement has similar terms as the 2022 NCI License Agreement for payments related to minimum annual royalties, non-royalty revenue, PRV and consideration from assignment of the 2023 NCI License Agreement or in connection with a change in control.

Components of operating results

Operating expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and development expenses

Our research and development expenses consist of:

- direct costs, including:
    - costs related to the production of preclinical and clinical materials, including fees, milestones and royalties paid to contract manufacturers,
    - expenses incurred under agreements with consultants and third-party contract organizations that conduct research and development activities on our behalf,
    - laboratory supplies and materials used for internal research and development activities,
    - laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials,
    - health authority filing fees costs related to sponsored research service agreements, and
    - costs incurred in obtaining technology licenses or in-process research and development (IPR&D) assets through asset acquisitions if the technology or IPR&D has not reached technological feasibility and has no alternative future use.
- indirect costs, including:
    - personnel-related costs, such as salaries, benefits and stock-based compensation expenses for employees engaged in research and development functions, and
    - facilities-related costs, depreciation and other miscellaneous costs.

We expense all research and development costs in the periods in which such costs are incurred. Costs for certain research and development activities are recognized based on evaluating the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers. Non-refundable advance payments for goods and services used over time for research and development are capitalized and recognized as goods are delivered or as the related services are performed. In-licensing fees and other costs to acquire technologies used in research and development that have not yet received regulatory approval and that are not expected to have an alternative future use are expensed when incurred. Because we are working on multiple research and development programs at any one time, we track our direct costs by the stage of program, clinical or preclinical. However, our indirect costs are not directly tied to any one program and are deployed across multiple programs. As such, we do not track indirect costs on a specific program basis.

As of the date of this prospectus, 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 personnel-related costs, costs related to maintenance and filing of intellectual property and other expenses for outside professional services, including

legal, human resources, audit, and accounting services, as well as facilities-related costs not included in research and development expenses. Personnel-related costs consist of salaries, bonuses, benefits and stock-based compensation costs for our executive, finance, and general and administrative personnel. 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, which will also increase our general and administrative expenses. Following this offering, we also expect that our costs will increase 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 expenses that we did not incur as a private company.

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.

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.

Results of operations

Comparison of the six months ended June 30, 2022 and 2023

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

(in thousands) (unaudited)	Six months ended June 30, 2022	2023	Change amount
Operating expenses:			
Research and development	$ 11,673	$ 26,491	$ 14,818
General and administrative	2,044	6,552	4,508
Total operating expenses	13,717	33,043	19,326
Loss from operations	(13,717)	(33,043)	(19,326)
Interest expense	(776)	(1,604)	(828)
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	(692)	(692)
Change in fair value of derivative liabilities	(407)	6,453	6,860
Loss on extinguishment of convertible notes	—	(2,316)	(2,316)
Other income (expense), net	(17)	603	620
Net loss and comprehensive loss	$ (14,917)	$ (30,599)	$(15,682)

Research and development expenses

Our research and development expenses for each of the periods indicated are summarized by class in the table below:

(in thousands) (unaudited)	Six months ended June 30, 2022	2023	Change amount
Direct costs:			
Contract manufacturing	$ 3,441	$ 10,354	$ 6,913
Preclinical and clinical outside services	259	2,468	2,209
Consulting and professional services	1,539	342	(1,197)
Laboratory supplies and materials	1,528	2,677	1,149
Acquired in-process research and development	850	466	(384)
Indirect costs:			
Personnel-related costs including stock-based compensation	2,923	7,391	4,468
Facilities-related and other	1,133	2,793	1,660
Total research and development expenses	$ 11,673	$ 26,491	$14,818

Research and development expenses increased by $14.8 million to $26.5 million in the six months ended June 30, 2023 compared to $11.7 million in the six months ended June 30, 2022. This increase was primarily driven by an increase of $6.9 million in contract manufacturing costs, as well as increases in personnel-related costs of $4.5 million, preclinical and clinical outside services of $2.2 million, and laboratory supplies and materials of $1.1 million as we progressed CRG-022 and continued the development of our manufacturing process in preparation for our Phase 2 clinical trial starting in the third quarter of 2023 and increased headcount on our research and development teams to support our development efforts. Facilities-related and other expenses increased by $1.7 million related to our new facilities lease entered into in February 2023.

Consulting and professional services decreased by $1.2 million primarily due to a $0.5 million decrease in recruiting costs and a $0.7 million decrease in consulting expenses due to reduced reliance on external consultants and professional services to support clinical development and technical operations activities as we increased headcount on our research and development teams.

General and administrative expenses

Our general and administrative expenses for each of the periods indicated are summarized by class in the table below:

(in thousands) (unaudited)	Six months ended June 30, 2022	Six months ended June 30, 2023	Change amount
Personnel-related costs, including stock-based compensation	$ 839	$ 2,355	$ 1,516
Professional services	1,028	3,921	2,893
Facilities-related and other	177	276	99
Total general and administrative expenses	$ 2,044	$ 6,552	$ 4,508

General and administrative expenses increased by $4.5 million to $6.5 million in the six months ended June 30, 2023 compared to $2.0 million in the six months ended June 30, 2022. This increase was primarily driven by an increase of $2.9 million in professional services related to accounting and audit costs, as well as an increase in outsourced human resource services, and an increase of $1.5 million in personnel-related costs due to a higher headcount in our finance and administrative personnel.

Interest expense

Interest expense increased by $0.8 million to $1.6 million in the six months ended June 30, 2023 compared to $0.8 million in the six months ended June 30, 2022. This increase was attributable to additional issuances of convertible notes. The outstanding balance of our convertible notes increased from $8.1 million as of June 30, 2022 to $24.9 million prior to the conversion of the 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 was a net loss of $0.7 million in the six months ended June 30, 2023 primarily due to an estimated increase in the fair value of the underlying shares of our Series A-1 redeemable convertible preferred stock at the expected settlement dates. There were no redeemable convertible preferred stock tranche obligations in the six months ended June 30, 2022.

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 the six months ended June 30, 2023 compared to a loss of $0.4 million in the six months ended June 30, 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 the six months ended June 30, 2023. The terms of the convertible notes were amended in February 2023 to convert the notes into shares of our Series A-2 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.

Comparison of the years ended December 31, 2021 and 2022

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

(in thousands)	Year ended December 31, 2021	2022	Change amount
Operating expenses:			
Research and development	$ 4,461	$ 29,373	$ 24,912
General and administrative	1,516	5,398	3,882
Total operating expenses	5,977	34,771	28,794
Loss from operations	(5,977)	(34,771)	(28,794)
Interest expense	—	(4,942)	(4,942)
Change in fair value of derivative liabilities	—	(1,216)	(1,216)
Other income (expense), net	127	(22)	(149)
Net loss and comprehensive loss	$ (5,850)	$ (40,951)	$(35,101)

Research and development expenses

Our research and development expenses for each of the periods indicated are summarized by class in the table below:

(in thousands)	Year ended December 31, 2021	2022	Change amount
Direct costs:			
Contract manufacturing	$ 1,391	$ 10,413	$ 9,022
Consulting and professional services	1,804	2,058	254
Laboratory supplies and materials	39	3,270	3,231
Preclinical and clinical outside services	33	2,063	2,030
Acquired in-process research and development	—	1,013	1,013
Indirect costs:			
Personnel-related costs including stock-based compensation	927	8,307	7,380
Facilities-related and other	267	2,249	1,982
Total research and development expenses	$ 4,461	$ 29,373	$24,912

Research and development increased by $24.9 million in 2022 compared to 2021. This increase was primarily driven by an increase of $9.0 million in contract manufacturing expenses, as well as increases in personnel-related costs of $7.4 million, laboratory supplies and materials of $3.2 million, and preclinical and clinical outside services of $2.0 million as we increased our investments in research and development as we progressed CRG-022 and continued the development of our manufacturing process in preparation for our Phase 2 clinical

trial starting in the third quarter of 2023 and increased headcount to support these investments. Facilities-related and other expenses increased by $2.0 million primarily due to expenses related to our new facility lease entered into in November 2021. Acquired in-process research and development increased by $1.0 million primarily due to upfront fees paid on license arrangements entered into with Stanford University, Oxford and the NCI.

General and administrative expenses

Our general and administrative expenses for each of the periods indicated are summarized by class in the table below:

(in thousands)	Year ended December 31, 2021	2022	Change amount
Personnel-related costs including stock-based compensation	$ 812	$ 2,275	$ 1,463
Professional services	614	2,745	2,131
Facilities-related and other	90	378	288
Total general and administrative expenses	$ 1,516	$ 5,398	$ 3,882

General and administrative expenses increased by $3.9 million in 2022 compared to 2021. This increase was primarily driven by a $2.1 million increase in professional services primarily due to an increase in legal fees, as well as outside accounting and corporate services, a $1.5 million increase in personnel-related costs due to higher headcount in our finance and administrative personnel, and a $0.3 million increase in facilities-related and other expenses primarily due to expenses related to our facility lease entered into in November 2021.

Interest expense

Interest expense of $4.9 million for the year ended December 31, 2022 was related to the issuance of convertible notes in 2022. There were no convertible notes issued or outstanding in 2021.

Change in fair value of derivative liabilities

The change in fair value of derivative liabilities associated with our convertible notes was $1.2 million in 2022. There were no derivative liabilities in 2021 as we did not issue any convertible notes during the year.

Liquidity and capital resources

Since our inception, we have funded our operations primarily with the proceeds from the sale and issuance of our convertible preferred stock and from convertible notes. During the six months ended June 30, 2023, we raised aggregate net cash proceeds of $71.6 million from the sale and issuance of our convertible preferred stock and convertible notes, net of issuance costs. To date, we have incurred significant losses and negative cash flows from operations. As of June 30, 2023, we had available cash and cash equivalents of $42.4 million, which is available to fund operations, and an accumulated deficit of $77.6 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. Our existing cash as of June 30, 2023 and the proceeds of $45.9 million and $86.0 million from the issuances of our Series A-1 redeemable convertible preferred stock in July 2023 and October 2023, respectively, will not be sufficient to fund our operations for at least one year from the issuance date of our financial statements. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments or classifications that may result from our possible inability to continue as a going concern. However, based on our current operating plans, we estimate that our existing cash and cash equivalents,

together with the net proceeds from this offering, 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 amended to convert 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 SPA) 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 SPA includes two additional tranche closings for 3,381,941 shares and 6,341,148 shares, respectively, at a purchase price of $13.57 per share. We completed the second and third tranche closings in July 2023 and October 2023, respectively, for gross proceeds of $45.9 million and $86.0 million, respectively.

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 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; 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. 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, credit or 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. 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:

	Six months ended June 30,		Year ended December 31,	
(in thousands) (unaudited)	**2022**	**2023**	**2021**	**2022**
Cash used in operating activities	$ (9,246)	$ (28,965)	$ (4,942)	$ (29,072)
Cash used in investing activities	(1,442)	(2,113)	(442)	(3,282)
Cash provided by financing activities	17,490	71,577	5,414	34,185
Net increase in cash and cash equivalents	$ 6,802	$ 40,499	$ 30	$ 1,831

Operating activities

Cash used in operating activities of $29.0 million for the six months ended June 30, 2023 was primarily attributable to our net loss of $30.6 million, partially offset by a $0.9 million decrease in our working capital and $0.7 million in non-cash adjustments. Non-cash adjustments consisted primarily of a $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, $1.6 million in noncash interest expense primarily

related to additional issuances of our convertible notes, $1.0 million in amortization of right-of-use asset, $0.7 million related to the net change in fair value of tranche obligations related to our Series A-1 redeemable convertible preferred stock, $0.6 million in stock-based compensation, $0.5 million in acquisition of in-process research and development primarily related to upfront fees accrued upon entering into the 2023 NCI License Agreement and $0.5 million in depreciation, partially offset by a $6.5 million gain from the change in fair value of derivative liabilities related to our convertible notes. The $0.9 million decrease in working capital is primarily due to a $5.9 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 contract manufacturing services, preclinical and clinical outside services and personnel expenses, partially offset by a $3.8 million increase in other assets primarily related to a deposit paid for clinical trial services, a $0.9 million decrease in operating lease liability and a $0.3 million increase in prepaid expenses and other current assets.

Cash used in operating activities of $9.2 million for the six months ended June 30, 2022 was primarily attributable to our net loss of $14.9 million, partially offset by $2.9 million in non-cash adjustments and a $2.8 million decrease in our working capital. Non-cash adjustments consisted primarily of $0.8 million in noncash interest expense and $0.4 million in change in fair value of derivative liabilities related to our convertible notes, $0.5 million in amortization of right-of-use asset, $0.9 million in acquisition of in-process research and development primarily related to upfront fees incurred upon entering into the 2022 NCI License Agreement and the Oxford Agreement, $0.1 million in depreciation and $0.2 million in stock-based compensation. The $2.8 million decrease in working capital is primarily due to a $4.6 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 contract manufacturing services, partially offset by a $1.2 million increase in prepaid expenses and other current assets primarily related to prepayments for the anticipated manufacturing activities, $0.1 million increase in other assets and a $0.5 million decrease in operating lease liability.

Cash used in operating activities of $29.1 million for the year ended December 31, 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 Agreement, the Oxford Agreement and the Stanford License Agreement, $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 contract manufacturing 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 contract manufacturing 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.

Cash used in operating activities of $4.9 million for the year ended December 31, 2021 was primarily attributable to our net loss of $5.9 million, partially offset by $0.7 million in non-cash adjustments and a $0.3 million decrease in our working capital. Non-cash adjustments consisted primarily of $0.5 million in stock-based compensation and $0.1 million in amortization of right-of-use asset. The decrease in working capital was primarily due to a $1.0 million increase in accounts payable, accrued clinical and research and development costs, and accrued expenses and other current liabilities driven by increased research and development

expenses, partially offset by a $0.4 million increase in other non-current assets related to payroll tax credit and a deposit paid upon execution of our lease in San Mateo, California, a $0.2 million decrease in operating lease liability and a $0.1 million increase in prepaid expenses and other assets.

Investing activities

Cash used in investing activities of $2.1 million for the six months ended June 30, 2023 consisted of $2.0 million in purchases of equipment for our research and development activities and $0.1 million from the purchase of in process research and development comprised of upfront fees paid upon entering into the 2023 NCI License Agreement.

Cash used in investing activities of $1.4 million for the six months ended June 30, 2022 consisted of $1.1 million in purchases of equipment for our research and development activities and $0.3 million from the purchase of in process research and development comprised of upfront fees paid upon entering into the 2022 NCI License Agreement and the Oxford Agreement.

Cash used in investing activities of $3.3 million for the year ended December 31, 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 Agreement, the Oxford Agreement and the Stanford License Agreement.

Cash used in investing activities of $0.4 million for the year ended December 31, 2021 consisted of $0.4 million in purchases of equipment for our research and development activities.

Financing activities

Cash provided by financing activities of $71.6 million for the six months ended June 30, 2023 primarily consisted of $68.1 million in net proceeds from issuance of 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 $17.5 million for the six months ended June 30, 2022 primarily consisted of $12.0 million in net proceeds from issuance of convertible notes, of which $6.4 million was from related parties, and $5.5 million in net proceeds from issuance of convertible preferred stock.

Cash provided by financing activities of $34.2 million for the year ended December 31, 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 sale and issuance of shares of our Series Seed convertible preferred stock, and $0.2 million from the sale and issuance of restricted stock awards.

Cash provided by financing activities of $5.4 million for the year ended December 31, 2021 consisted of $5.4 million in net proceeds from sale and issuance of shares of our Series Seed convertible preferred stock.

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, including amendments, for a certain facility, which comprises office and laboratory space, through November 2024. As of June 30, 2023, our fixed lease payment obligations are $3.8 million, with $2.8 million 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 are not known, we have not included these fees in our balance sheets as of June 30, 2023. For a more detailed description of these agreements, see the section titled “Business—License agreements.”

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 audited financial statements and Note 2 to our unaudited interim condensed financial statements appearing elsewhere in this prospectus, 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 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 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 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. 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.

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* – See the subsection titled "–*Common stock valuations*" below.

- *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* – 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.

Stock-based compensation expenses were $0.5 million and $0.3 million for the years ended December 31, 2021 and 2022, respectively, and $0.2 million and $0.6 million for the six months ended June 30, 2022 and 2023, respectively. As of June 30, 2023, we had $6.9 million of total unrecognized stock-based compensation expense related to stock options, which we expect to recognize over a weighted-average period of 2.7 years. As of June 30, 2023, we had $0.1 million of total unrecognized stock-based compensation expense related to outstanding restricted stock awards, which we expect to recognize over a weighted-average period of 2.6 years.

The intrinsic value of all outstanding options as of June 30, 2023, was approximately $22.1 million, based on the initial public offering price of $15.00 per share, of which approximately $0.7 million was related to vested options and approximately $21.4 million was related to unvested options.

Common stock valuations

As there has been no public market for our common stock to date, the estimated fair value of our common stock underlying our share-based awards were estimated on each grant date by our management and approved by our board of directors. Our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development, the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock, our financial condition and operating results, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of marketability of our common stock. Valuations of our common stock were prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the Practice Aid).

For our valuations performed prior to April 21, 2023, our board of directors determined the market approach and option pricing method (OPM) were the most appropriate methods for allocating our enterprise value. Under the market approach, we estimated the value based upon our prior sales of preferred stock to unrelated third parties. We then applied these derived multiples or values to our financial metrics to estimate our market value.

The allocation of these enterprise values to each part of our capital structure, including our common stock and convertible preferred stock, was done utilizing the OPM. The OPM treats the rights of the holders of preferred and common stock as equivalent to call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred stock, as well as their rights to participation and conversion. Thus, the estimated value of the common stock can be determined by estimating the value of its portion of each of these call option rights. The OPM derives the implied equity value of a company from a recent transaction involving our own securities issued on an arms-length basis.

For our valuations performed since April 21, 2023, our board of directors determined the hybrid method was the most appropriate method for determining the fair value of our common stock. The hybrid method is a hybrid between the probability-weighted expected returns method (PWERM) and the OPM. Using the PWERM, the enterprise value under various exit scenarios including an initial public offering (IPO) and staying private that considered our estimate of the timing of each scenario and were weighted based on our estimate of the probability of each event occurring. Our equity value under the IPO scenario was estimated using the market approach based on recent IPO values of comparable companies. The equity value under the IPO scenarios was allocated to our capital stock using an IPO scenario analysis that contemplates the timing, size, valuation, and probability of an IPO event in the future. The stay private scenario estimated our equity value using a market approach based on the second tranche closing of our Series A redeemable convertible preferred stock. The equity value was then allocated to our capital stock based on the OPM. The equity value under all scenarios was reduced by a discount for lack of marketability.

For valuations after the completion of this offering, the fair value of each share of underlying common stock will be based on the closing price of our common stock as reported on the date of grant on the primary stock exchange on which our common stock is traded.

Emerging growth company and smaller reporting company status

We expect to be an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. 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 may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as 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 audited financial statements and Note 2 to our unaudited interim condensed financial statements included elsewhere in this prospectus for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

Quantitative and qualitative disclosures about market risk

Market risk represents the risk of loss that may impact our financial position because of adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of exposure resulting from potential changes in interest rates, exchange rates or inflation. We do not hold financial instruments for trading purposes.

Interest rate risk

Our cash and cash equivalents consist of cash held in readily available checking and money market accounts. As of June 30, 2023, we did not hold any financial instruments for trading purposes. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates.

Foreign currency

We contract with vendors in foreign countries, primarily in the United Kingdom. We are therefore subject to fluctuations in foreign currency rates in connection with these agreements. We do not hedge our foreign currency exchange rate risk.

Net realized and unrealized gains and losses from foreign currency transactions are reported in other income (expense), net, in the statements of operations and comprehensive loss. The impact of foreign currency costs on our operations has been negligible for all periods presented.

Inflation risk

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

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 and trafficking to tumor lesions, 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 costimulation 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 CAR T-cell product candidate designed to address resistance mechanisms by targeting CD22, an alternate tumor antigen that is expressed in a vast majority of B-cell malignancies. We exclusively licensed the underlying autologously derived CAR for CRG-022 from the National Cancer Institute (NCI). Prior to our licensing the underlying CAR from 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. As of the most recent data cutoff date (May 3, 2023), the following results were reported:

- CR rate of 53% (20 of 38 patients);
- responses were durable with 85% of patients (17 of 20 patients) that achieved a CR maintained their response with a median follow up time of 23 months and a maximum of 43 months;
- only 3 of the 20 patients who achieved a CR have relapsed;
- overall response rate (ORR) of 68% (26 of 38 patients), which was statistically significant;
- median overall survival (OS) of 14.1 months;

- only 1 patient experienced Grade 3 or higher cytokine release syndrome (CRS), which happens when a patient's immune system responds to an infection or immunotherapy more aggressively than it should;
- 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. 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 (IND) application. We understand that Stanford may pursue additional clinical trials of a similar CAR T 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 we anticipate Stanford will be 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 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 and STASH platforms, 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 costimulation (e.g., 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 costimulatory domain into the tri-specific CAR T cell to counter a target-independent mechanism, the downregulation of CD58 (the ligand of the CD2 costimulatory 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 costimulation, which involves interaction of one or more costimulatory 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

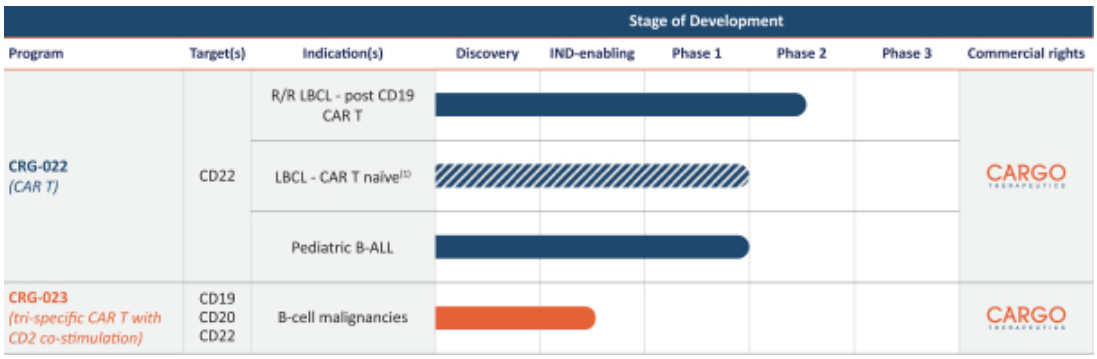
for the costimulatory receptors. Alteration of CD58 expression is associated with poor prognosis in patients with LBCL and leads to lack of response to CD19 CAR T cells. Approximately 25% of LBCL patients that are eligible for CAR T-cell therapy have mutated or absent CD58 and up to 67% have decreased 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.

Our second platform technology, which we refer to as STASH, is designed to enable multiplex engineering of a variety of immune cell types. This platform allows us to incorporate multiple transgene therapeutic “cargo” designed to enhance CAR T-cell persistence and trafficking to tumor lesions, as well as to help safeguard against tumor resistance and T-cell exhaustion. As is common among CAR T cell therapies, we use a virus, in the form of a lentiviral vector to deliver the genetic elements that modify the T cell. Engineering a multifunctional cell requires the introduction of additional genetic elements that often do not fit within a single lentiviral vector, requiring the use of multiple vectors. However, engineering cells with multiple vectors typically results in a heterogeneous cell product, and we are unaware of an efficient way to generate a homogenous CAR T-cell product using existing viral vector systems. Our STASH platform is designed to address this problem by employing a technology that selects only cells that possess all of the desired transgenes, which enables the production of a homogeneous population of CAR T cells produced using more than one delivery vector. We believe this technology will allow us to efficiently incorporate more genetic elements into our CAR T cells with the goal of enhancing the potential for efficacy, persistence and safety.

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 application 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. Notwithstanding the foregoing, 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. 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 intend to discuss with the FDA 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 costimulatory 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. The median OS was 14.1 months. As of the May 3, 2023 cutoff date, the Phase 1 clinical trial demonstrated a 53% CR with 17 of 20 patients that achieved a CR maintained their response with a median follow up time of 23 months and a maximum of 43 months, which we believe suggests favorable durability.

CRG-022 was generally well-tolerated, as of the cutoff date, with only one patient 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 deescalation back to the first dose level. Given this result, it was determined that the Phase 2 optimal dose was the first dose level of 1×10^6 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 have been actively engaged with the FDA in 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. We expect interim results from this Phase 2 clinical trial in 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.

***O**ur tri-specific program, CRG-023*

Our most advanced preclinical program, CRG-023, incorporates a tri-specific CAR designed to address tumor antigen loss and our CD2 platform technology to address loss of costimulatory 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 costimulatory domain into the tri-specific CAR T to counter a target-independent mechanism, the downregulation of CD58 (the ligand of the CD2 costimulatory 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 history, team and investors

We were founded by pioneers and world experts in CAR T-cell therapy, and we have built a seasoned leadership team with experience and success developing, manufacturing, launching and commercializing oncology and cell therapy products.

Our founders include internationally recognized experts from Stanford and an acclaimed cancer advocate. Crystal Mackall, MD, Professor of Pediatrics and Internal Medicine at Stanford serves as Founding Director of the Stanford Center for Cancer Cell Therapy, Associate Director of Stanford Cancer Institute, Leader of the Cancer Immunology and Immunotherapy Program, and Director of the Parker Institute for Cancer Immunotherapy at Stanford. Dr. Mackall previously served as Chief of the Pediatric Oncology Branch at the NCI. Robbie Majzner, MD, is the Director of the Pediatric and Young Adult Cancer Cell Therapy Program within the Departments of Pediatric Oncology and Medical Oncology at Dana Farber Cancer Institute and the Division of Hematology/Oncology at Boston Children's Hospital. Dr. Majzner's laboratory is working to develop novel cellular immunotherapies for children with incurable cancers. Louai Labanieh, PhD is a Parker Scholar at Stanford School of Medicine and is a leader in engineering CAR T cells using synthetic biology. Nancy Goodman, JD, is the CEO of Kids v Cancer, a nonprofit organization dedicated to policy reform to attract biotech and pharmaceutical companies to pediatric cancer drug development.

Our management team has significant experience in both cell therapy and oncology. We have progressed products from research to clinical trials, and ultimately to regulatory approval and commercialization. Gina Chapman, our President and Chief Executive Officer, brings over 30 years of biopharmaceutical commercial and operational experience. She most recently served as Senior Vice President and Business Unit Head at Genentech, where she worked for more than 15 years. Michael Ports, PhD, our Chief Scientific Officer, has over 10 years of biopharmaceutical and cell-therapy drug development experience. He most recently served as Vice President and Head of Cell Therapy Discovery and Platforms at Janssen. Shishir Gadam, PhD, our Chief Technical Officer, most recently was Vice President of Global Cell Therapy Manufacturing Science and Technology at Bristol Myers Squibb (BMS). He played an instrumental role in the global licensure and launch of the CAR T-cell products Breyanzi and Abecma and built a global manufacturing science and technology organization responsible for product and process life-cycle management, technology transfers and manufacturing technology. Anup Radhakrishnan, our Chief Financial Officer and Chief Business Officer, brings over 20 years of experience in the biopharmaceutical sector providing strategic financial leadership across both clinical and commercial stage organizations. He previously served as CFO at Dascena and worked at Genentech for over 11 years. 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. As a result, we believe having a management team with significant relevant experience positions us well to overcome these challenges.

We are also supported by our board of directors, scientific advisory board and a leading syndicate of investors.

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 interim results from this Phase 2 clinical trial in 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 and trafficking to tumor lesions, 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 costimulatory 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 costimulation. Tumors evolve to escape CAR T-cell destruction through the downregulation of cognate ligands for costimulatory signaling molecules. For example, CD58 is the ligand of the CD2 costimulatory 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 costimulation 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 CAR T 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.

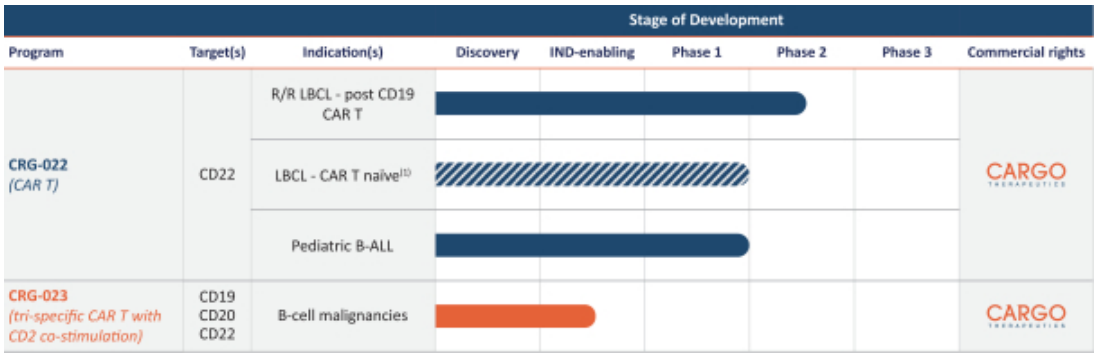
Our solution: next generation of potential CAR T-cell therapies

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 costimulatory signaling, such as tumor cells downregulating CD58 expression. Because these mechanisms are not antigen-specific, loss of costimulation can lead to broad suppression of immune therapies. We are working to address loss of costimulatory ligands such as CD58, by creating CAR T cells that can induce CD2 costimulatory 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

Our 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. Our initial focus is to treat patients with high unmet need and poor survival outcomes who develop resistance to current guideline recommended cancer therapies, and 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 product candidates designed to address key mechanisms of resistance for the treatment of a variety of cancers. In addition to these product candidates, we are also advancing our proprietary platform technologies, including our CD2 and STASH platforms, to develop effective multi-specific and multi-functional cancer therapies.



(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 intend to discuss with the FDA initiation of a Phase 2 program in LBCL – CAR T naïve without completing earlier clinical trials in LBCL – CAR T-naïve patients.

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. We expect interim results from this Phase 2 clinical trial in 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 chemoimmunotherapy 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 chemoimmunotherapy 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.

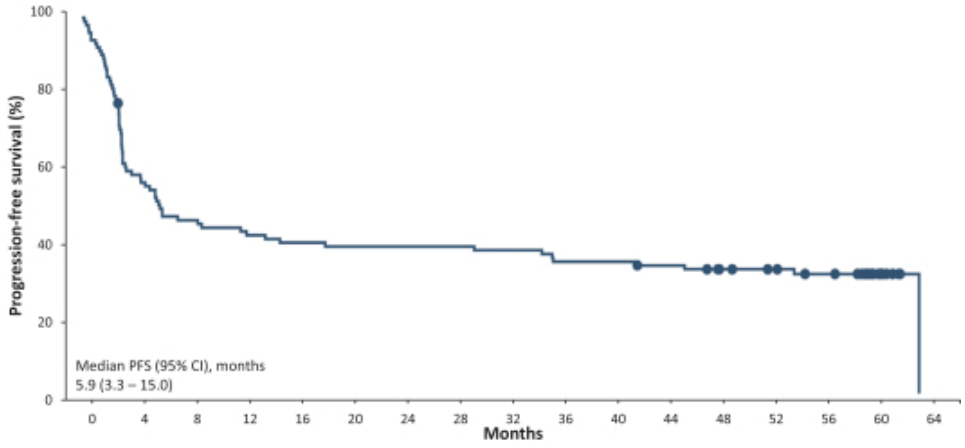


Figure 1. As seen in the Phase 2 clinical trial (ZUMA-1) of Yescarta, approximately 60% percent of patients were observed to not obtain a long-term benefit from CD19 CAR T-cell therapy

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 costimulatory 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.

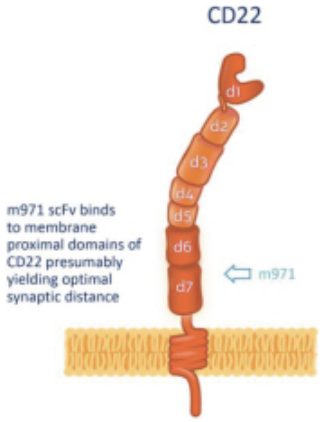


Figure 2. The m971 antigen-binding domain incorporated into the CD22 CAR binds to a membrane proximal domain of CD22

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/R CD22+ 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.

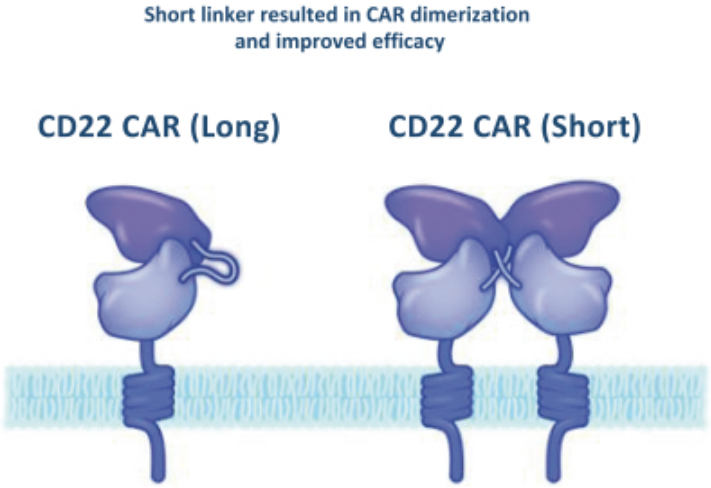


Figure 3. Incorporation of a short linker resulted in increased activity of the CD22 CAR used to create CRG-022

4-1BB costimulatory 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 costimulatory domains and activation domains. Approved CAR T-cell therapies incorporate costimulatory domains from CD28 or from 4-1BB and an activation domain from CD3ζ. It has been shown in a third-party study that the choice of costimulatory domain influences the persistence and memory phenotype of CAR T Cells. The inclusion of a 4-1BB costimulatory 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 costimulatory 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% of 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 application 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 May 3, 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 10^6 CD22 CAR+ cells/kg] and DL2 [3 x 10^6 CD22 CAR+ cells/kg]). As shown in the figure below, as of the May 3, 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)	Tot (N = 38)
Median follow up, months [range]	21.2 [5.9-43.1]	34.2 [28.9-37.8]	22.8 [5.9-43.1]
Overall Response Rate (ORR)*, n (%)	19 (66%)	7 (78%)	26 (68%)
CR Rate	15 (52%)	5 (56%)	20 (53%)

Figure 4. ORR and CR observed in Phase 1 clinical trial with CRG-022 as of May 3, 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.

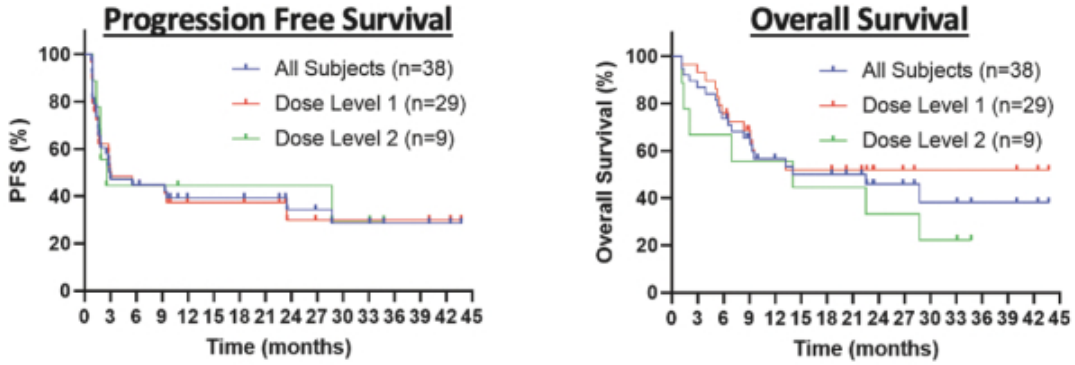


Figure 5. PFS and OS of LBCL patients treated with CRG-022 as of May 3, 2023

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 experienced Grade 3 CRS at DL2. 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
Cytokine Release Syndrome, n (%)			
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%)
Neurologic Events / ICANS, n (%)			
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 May 3, 2023

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 effector 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 multiorgan 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 Phase 2 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. 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. We expect interim results from this Phase 2 clinical trial in 2025.

Following fludarabine/cyclophosphamide conditioning, patients will be dosed with 1 x 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.

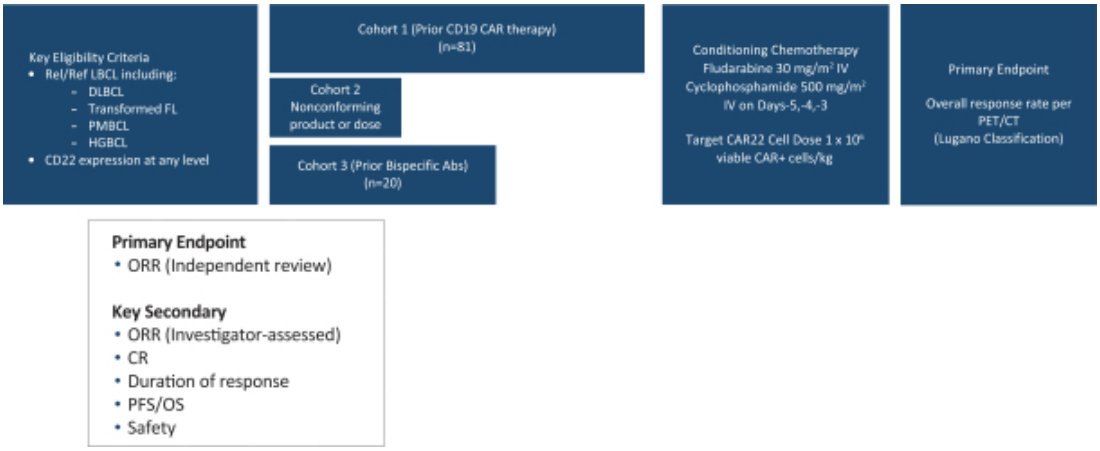


Figure 7. Design of our potentially pivotal Phase 2 clinical trial of CRG-022

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 have already 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 costimulation platform technology and CRG-023, a tri-specific CAR T product candidate

Our first platform technology involves the integration of a CD2 costimulatory 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 costimulation, which involves interaction of one or more costimulatory 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 costimulatory receptors. These ligands include CD58, the ligand of the CD2 costimulatory 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 costimulatory 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 costimulation 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 costimulation 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 costimulatory ligands

The loss of cell surface costimulatory proteins on tumors that function to activate T-cell costimulatory 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.

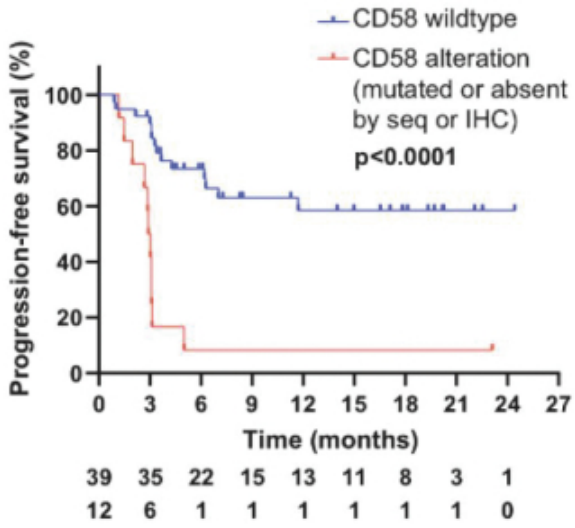


Figure 8. Alteration in CD58 expression was associated with poor prognosis in DLBCL patients treated with Yescarta.

This phenomenon is not confined to DLBCL. A study published in June 2023 demonstrated downregulation 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 (BiTEs), 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.

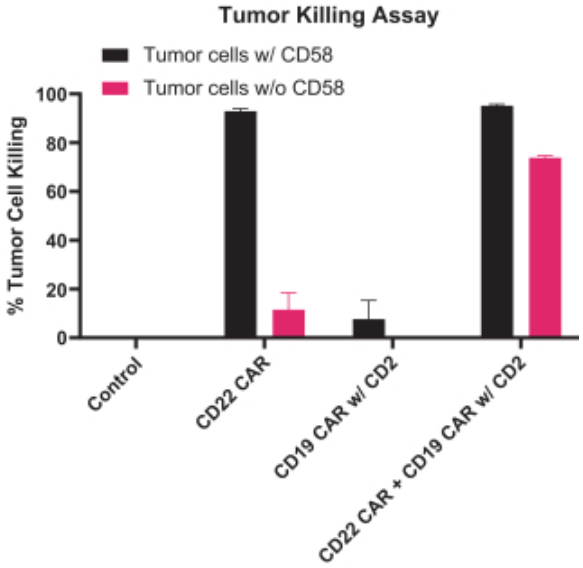


Figure 9. Multispecific CAR T cells incorporating our CD2 technology achieves sustained killing of both CD58+ and CD58- tumor cells

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 costimulation 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.

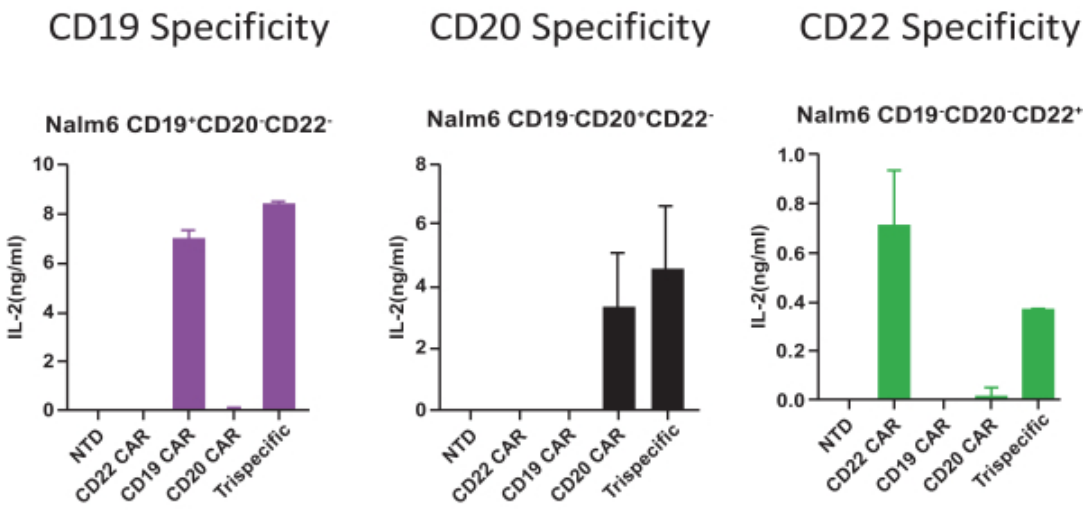


Figure 10. Each CAR in the CARGO tri-specific induced the T cells to secrete IL-2 in response to antigen at levels similar to the mono-specific CAR T.

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).

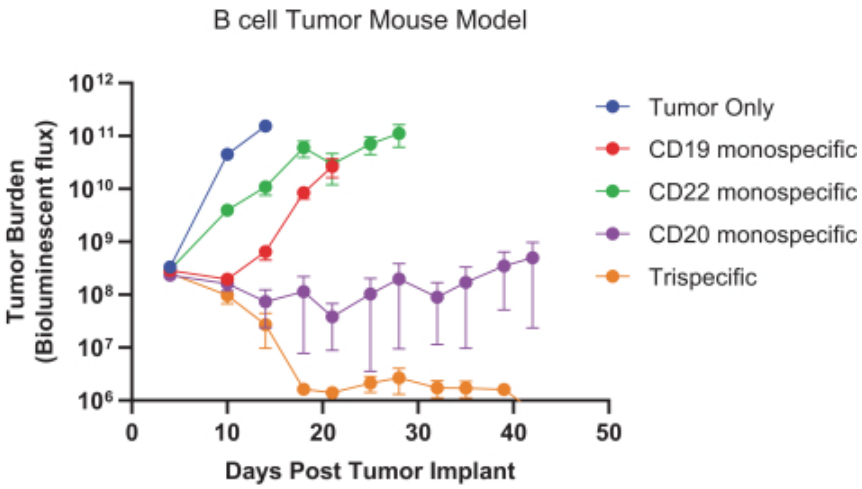


Figure 11 Our tri-specific CAR T cells showed better in vivo antitumor activity against a mouse B cell tumor model than mono-specific CAR T cells.

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 (Figure 14). 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.

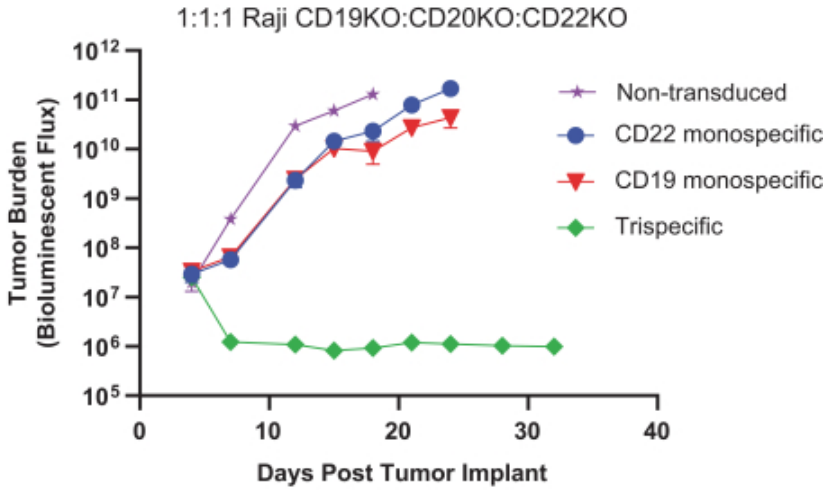


Figure 12. Our tri-specific CAR T cells reduced tumor burden to background levels in an antigen loss in vivo model.

We are initiating IND-enabling studies with CRG-023.

Our STASH platform technology, facilitating homogeneous multicomponent cell therapies

We believe CAR T cells that target more than one antigen on a tumor can address the resistance caused by antigen downregulation or loss on tumor cells, a potential point of failure for monospecific CARs. In addition, there is the potential of increasing persistence or improving tolerability of these cells by driving the expression of proteins such as cytokines that can increase the ability of immune cells to attack tumor cells. However, current technologies to deliver the constructs required to create these multicomponent cell therapies are limited by the capacity of the vectors which results in the need to introduce multiple vectors into T cells. Creating a homogenous population of T cells, each containing copies of all the desired constructs, represents a technical challenge, especially considering the challenges associated with commercial scalability. We believe our STASH technology has broad potential application in all of these scenarios by enabling the incorporation of multiple components without creating heterogeneity.

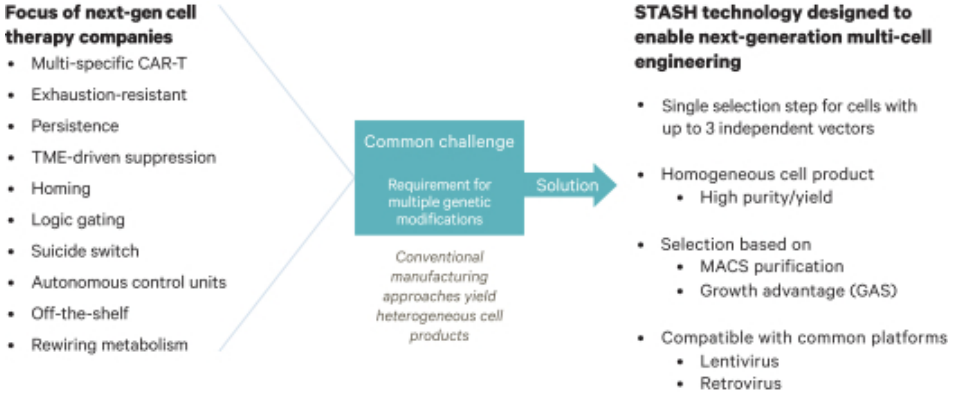


Figure 13. STASH is a technology that can potentially be applied to facilitate the manufacturing of cell therapies incorporating more than one vector.

We have exercised our exclusive option, pursuant to a license agreement between us and Stanford, to a proprietary technology called STASH that is designed to specifically address this problem and allow the manufacturing of homogenous CAR T cells that incorporate multiple vectors. STASH technology comprises proprietary elements, referred to as STASH components, that are incorporated into each vector to be delivered to the CAR T cell. One of these STASH components expresses a marker that can be used to purify the T cells. However, this marker is only expressed on the surface of the T cell when all STASH components are present inside the cell. Therefore, only T cells that have received all vectors will express this tag on the cell surface, which allows them to be purified from the remaining cells that do not express this tag on the surface.

We are committed to improving T-cell activation and persistence and addressing immunosuppressive mechanisms in the tumor microenvironment. We believe that our CD2 and STASH technologies, 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 CBMG, Gilead Sciences, Gracell, ImmPACT Bio, Miltenyi, Novartis and Oncternal. Potential competitors with allogenic CAR cell therapies in development include Adicet Bio, Allogene Therapeutics, Atara Biotherapeutics, CRISPR Cellectis, Celyad, Fate, Nkarta, Precision Biosciences, Sana Biotechnology, Sorrento Therapeutics 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 of our programs are likely to be efficacy, safety and convenience.

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

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.

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).

Intellectual property

Intellectual property 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 procedures, non-disclosure agreements with third parties, and other contractual protections, to protect our intellectual property rights, including our proprietary technology, solutions, know-how and brands.

We seek to protect the intellectual property, or IP, and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our technologies and product candidates and methods of using the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. We likewise seek to protect the IP to which we obtain rights through licenses and sublicenses and work collaboratively with our licensors to ensure patent prosecution and protection. We also rely on trademarks, copyrights, trade secrets, know- how and continuing technological innovation to develop and maintain our proprietary and IP positions. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our IP and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable IP and proprietary rights of third parties.

As of August 4, 2023, we owned six pending U.S. patent applications and two pending PCT applications comprising applications drawn to the following technical subject matter: (a) cytokine receptor 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; and (g) lymphocyte-activation gene 3 constructs and uses thereof. Any patents issuing from these patent applications are expected to expire from 2043-2044, without taking into account any possible patent term adjustments or extensions. We have also exclusively licensed from NCI and Stanford or optioned six granted U.S. patents, four pending U.S. patent applications, one pending PCT application, 15 granted foreign patents (in Australia, China, Europe, Hong Kong, India, Japan and Russia), and 46 pending foreign patent applications (in Australia, Brazil, Canada, China, Europe, Hong Kong, Japan, Korea, Israel, India, 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), patents and comprising applications 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 patents and any patents issuing from these patent applications are expected to expire from 2029 to 2042, without taking into account any possible patent term adjustments or extensions.

Our ability to maintain and solidify our proprietary and IP position(s) for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and Patent Cooperation Treaty, or 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 technology in relation to the commercialization of our products. We also cannot predict the breadth of claims that may be allowed or enforced in any patents 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 can take many years to issue, there may be applications unknown to us, which applications 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, or 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 most countries, including the United States, 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, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent.

There can be no assurance that our pending provisional or PCT patent applications will ultimately result in issued patents or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in- license in the future. 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 coverage, 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 an adequate amount of time.

As of August 25, 2023, we had no outstanding litigation related to our intellectual property nor any threat to initiate claims against us. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how or to defend against claims of infringement of the rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such 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 intellectual property 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 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 contractual protections with employees, contractors and partners. We require our employees, consultants and other third parties to enter into confidentiality and proprietary rights 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 intellectual property 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 intellectual property.

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 Agreement). Pursuant to the terms of the Stanford Agreement, 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.

As consideration for the license granted under the Stanford Agreement, 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 $100,000 per year, up to $7.5 million for sales milestone payments, up to $3.98 million in development milestone payments for each therapeutic product covered by licensed patent rights that achieves specific clinical trials or regulatory approvals, up to $550,000 milestone payments upon achievement of specific commercial milestone events, a percentage of milestone payments applicable to products covered by licensed patent rights on the first two non-patented products in a range between 27% and 37% and, subject to certain royalty reductions, low single-digit percentage royalties on net sales of products that is covered by the licensed patent rights or licensed technology. Subject to the terms of the Stanford Agreement, 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 Agreement 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 Agreement 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 $250,000 if we are acquired by a third party or if we sell all or substantially all of our assets to which the Stanford Agreement relates.

Oxford license and supply agreement

In June 2022, we entered into a license and supply agreement (the 2022 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 2022 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 intellectual property 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 2022 Oxford Agreement, we paid Oxford Biomedica an upfront fee of $200,000. We also agreed to pay up to $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 and up to an aggregate of $4.25 million if certain milestones related to the transfer of manufacturing capabilities are achieved for each target. Additionally, we agreed to pay low single-digit percentage royalties on the net sales of the Licensed Products.

Pursuant to the terms of the 2022 Oxford Agreement, we solely own any and all intellectual property rights generated under the 2022 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 2022 Oxford Agreement, or require the use of such proprietary materials or our confidential information.

Unless terminated earlier, the 2022 Oxford Agreement will expire when we have no further payments due to Oxford Biomedica under the agreement. We may terminate the 2022 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 2022 Oxford Agreement. Either party

may terminate the 2022 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 2022 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 National Cancer Institute (the NCI) (the 2022 NCI License Agreement), pursuant to which the NCI grants to us a worldwide, royalty-bearing, exclusive 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-sublicenseable exclusive license to make, use, and import, but not sell, products (Allogenic Products) and to practice processes in the field of certain allogenic 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.

As consideration for the licenses granted under the 2022 NCI License Agreement, we agreed to pay the NCI a non-refundable license fee of $550,000, of which $175,000 was paid in 2022, and the remaining balance of $375,000 is payable in three equal annual installments beginning on the first anniversary of the effective date of the agreement. We accrued these non-refundable upfront fees on entering into the 2022 NCI License Agreement. We agreed to pay up to $150,000 in regulatory milestone payments upon achieving specific regulatory filing, 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 milestone upon achievement of specific commercial milestone events. Subject to the terms of the agreement, we also agreed to pay low single-digit percentage royalties on net sales of Autologous Products and Allogenic Products. We also agreed to pay the NCI a percentage (ranging from 5-10% on the low-end of the range to 15-25% on the high-end of the range) of non-royalty revenue received by us for granting a sublicence 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 $500,000 upon submission of each PRV for use by the FDA. We also agreed to pay the NCI a percentage (ranging from 2-7% on the low-end of the range to 7-12% on the high-end of the range) of the fair market value of the consideration we receive for any assignment of the 2022 NCI License Agreement to a non-affiliate (upon the NCI's prior written consent) or an allocated portion of the fair value of consideration received in connection with a change in control.

Unless earlier terminated, the 2022 NCI License Agreement will expire upon the expiration of the last to expire licensed patent right, but the exclusive license for evaluation purposes will expire two years from the effective date of the 2022 NCI License Agreement, with an option for us to extend the exclusive license for evaluation purposes for one year upon a non-creditable, nonrefundable payment of $50,000 to the NCI. The NCI may terminate or modify the 2022 NCI License Agreement 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 Agreement, 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 license agreement with the NCI (the 2023 NCI License Agreement) to acquire 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 both: receptors targeting CD19, CD20, and/or CD79b; and using STASH platform and/or a technology to activate CD2 signaling in the CAR T cell. As consideration for the license granted under the 2023 NCI License Agreement, we

agreed to pay the NCI a non-refundable license fee of $250,000 payable in three annual installments, and up to $90,000 in regulatory milestone payments upon achieving specific regulatory filing, up to $1.725 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 sublicence of the licensed patent rights. Additionally, in the event we are granted a PRV, we agreed to pay the NCI a minimum of $5 million upon the sale, transfer or lease of each PRV or $500,000 upon submission of each PRV for use by the FDA. We also agreed to pay the NCI a low single-digit percentage of the fair market value of the consideration that we receive for any assignment of the 2023 NCI License Agreement to a non-affiliate (upon the NCI's prior written consent) or an allocated portion of the fair value of consideration received in connection with a change in control.

Unless earlier terminated, the 2023 NCI License Agreement will expire upon the expiration of the last to expire licensed patent right. The NCI may terminate or modify the 2023 NCI License Agreement 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 Agreement, 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, record keeping, 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, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process 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 tests, animal studies and formulation studies in accordance with Good Laboratory Practice regulations, or GLPs, and other applicable regulations;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations, or GCPs, to evaluate the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a Biologics License Application, or 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 advisory committee review, if applicable;
- 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, or cGMPs, to assure 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 GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use 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 authorization from the FDA 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 the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. 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, within the 30-day time period, places the IND on a clinical hold. In such a case, 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 the investigational product to human subjects, and must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, 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 protocols detailing the objectives of the trial, dosing procedures, subject selection 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 submission to the existing IND must be made for each successive clinical trial conducted during product development 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 serious and unexpected suspected 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 consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. 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 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 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 with 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 and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must 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 testing in accordance with applicable regulatory requirements, the results of product development, including among other things, results, from nonclinical studies and clinical trials, are submitted to the FDA as part of a BLA requesting approval 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, controls, and proposed labeling, among other things. Data can come

from company-sponsored clinical studies, or from a number of 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 all BLAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information before FDA will review the application. Once filed, the FDA reviews a BLA to determine, among other things, whether the biologic is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. Under the Prescription Drug User Fee Act, or 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 make a "filing" decision.

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 as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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 assure compliance with GCPs. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or 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 clinical data, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may 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 a sponsor of an approved BLA to conduct post-marketing clinical trials designed to further assess a biologic's safety, purity or potency, 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, or 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 connection with the application. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of commercial products.

In addition, the Pediatric Research Equity Act, or 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 route of administrations. 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 for approval 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 biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or 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 designation of such biologic also entitles a party to 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 a 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 the development or review of a marketing application 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. Specifically, 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 the 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. With regard to a fast track product candidate, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor

provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy to expedite its development and review. A product candidate can receive Breakthrough Therapy 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 biological product candidates may also be eligible for regenerative medicine advanced therapy, or RMAT, designation. This designation may be available where the product candidate qualifies as an RMAT, meaning that, with limited exceptions, the product candidate is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products; the product candidate is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of Breakthrough Therapy, 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.

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or Breakthrough Therapy designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A 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, a product candidate may be eligible for accelerated approval. A biological product candidate intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of 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.

Fast track designation, Breakthrough Therapy RMAT designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

FDA regulation of companion diagnostics

We believe that certain of our product candidates may require an in vitro diagnostic to identify appropriate patient populations for investigation and/or use of our product candidates. These diagnostics, often referred to as companion diagnostics, are regulated 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, diagnostic tests 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 contemporaneously with the approval of the therapeutic 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 device 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 diagnostic device may be considered a significant risk device under the FDA’s Investigational Device Exemption (IDE) regulations. In which case, the sponsor of the diagnostic device will be required to submit and obtain approval of an IDE application, and subsequently comply with the IDE regulations. However, according to the guidance, if a diagnostic device 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 both the requirements of applicable 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 companion diagnostics 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 and adequate and 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 a diagnostic, the applicant must demonstrate that the diagnostic 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 Quality System Regulation (QSR), which imposes elaborate 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 then 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 can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, 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 are not maintained or problems are identified following initial marketing.

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

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of 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, 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 those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the 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 terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

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

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

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 the jurisdictions outside the United States. Violation of any of such laws or any other governmental regulations that apply may result in 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 drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates 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 any significant 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 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.

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 guidance 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. However, the Medicare drug price negotiation program is currently subject to legal challenges. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. The impact of the IRA on the pharmaceutical industry 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.

Facilities

Our corporate headquarters is located in San Mateo, California, where we lease approximately 15,400 square feet of office and laboratory space pursuant to a sublease agreement which was executed in November 2021 and expires in November 2024. In August 2022, we entered into an amendment to the sublease agreement, pursuant to which we expanded the leased premises for an additional 15,717 square feet of office and laboratory space, increasing the total leased premises to approximately 31,117 square feet at the existing San Mateo, California location through the original expiration date of November 2024.

We believe that our existing facilities are sufficient for our near-term needs but expect to need additional space as we grow. We believe that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Employees and human capital resources

As of June 30, 2023, we had 74 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.

Management

Executive officers and directors

The following table sets forth information regarding our executive officers, directors and key employees as of November 2, 2023:

Name	Age	Position(s)
Executive officers and employee directors:		
Gina Chapman	56	President, Chief Executive Officer and Director
Anup Radhakrishnan	44	Chief Financial Officer
Shishir Gadam, Ph.D.	56	Chief Technical Officer
Ginna Laport, M.D.	59	Chief Medical Officer
***Non-employee directors*:**		
John Orwin, MBA[1][2]	58	Director and Chairperson
Abraham Bassan	39	Director
Reid Huber, Ph.D.[2][3]	51	Director
David Lubner[1][2]	59	Director
Crystal Mackall, M.D.[4]	63	Director
Krishnan Viswanadhan, Pharm.D[1][3]	45	Director
Key employees:		
Halley Gilbert, J.D.	53	Chief Legal Officer
Michael Ports, Ph.D.	42	Chief Scientific Officer

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

(4) Dr. Mackall has resigned from our board of directors as of the effectiveness of the registration statement of which this prospectus is a part.

Executive officers and employee director

Gina Chapman has served as our President and Chief Executive Officer and as a member of our board of directors since May 2022. Prior to joining our company, from August 2007 to April 2022, Ms. Chapman worked at Genentech, Inc., a privately held biotechnology company and member of the Roche Group, where she held a number of roles of increasing responsibility. Most recently, from September 2021 to April 2022, Ms. Chapman served as Senior Vice President, Business Unit Head, Specialty and Chronic Care, and from April 2020 to November 2021, as Senior Vice President, Oncology/Hematology Business Unit Head. From May 2019 to April 2020, Ms. Chapman served as Vice President, U.S. Head, Avastin/Herceptin/Rituxan, and from August 2018 to April 2019, as Vice President, U.S. Head of Hemophilia. Ms. Chapman received a B.A. in Economics and Sociology from the University of California, Santa Barbara. We believe that Ms. Chapman is qualified to serve as a member of our board of directors due to her extensive experience as an executive in the biopharmaceutical industry across numerous therapeutic areas.

Anup Radhakrishnan has served as our Chief Financial Officer since August 2022. Prior to joining our company, from July 2021 to August 2022, Mr. Radhakrishnan served as Chief Financial Officer at Dascena Labs, LLC, an infectious disease and diagnostic testing lab, until it was acquired by CirrusDx in August 2022, and from April 2021 to July 2021, Mr. Radhakrishnan served as Vice President, Finance at Dascena. Prior to that, from January 2010 to April 2021, Mr. Radhakrishnan worked at Genentech, Inc., a privately held biotechnology company and member of

the Roche Group, in roles of increasing responsibility. From January 2020 to April 2021, he served as Senior Finance Director, Head of Access and External Affairs Finance, from June 2018 to April 2021, he served as Finance Lead, U.S. Breast and Skin Cancer Franchise and from July 2016 to January 2020, as Finance Director, Head of Managed Care and Customer Operations Finance. From July 2016 to April 2021, Mr. Radhakrishnan also served as Chief Financial Officer for the Genentech Patient Foundation. Before Genentech, Mr. Radhakrishnan held R&D finance roles of increasing responsibility at Elan Pharmaceuticals, CV Therapeutics and the University of California, San Francisco. Mr. Radhakrishnan received a B.A. in Finance from the University of San Francisco.

Shishir Gadam, Ph.D. has served as our Chief Technology Officer since January 2022. Prior to joining our company, from November 2019 to January 2022, Dr. Gadam served as Vice President of Global Cell Therapy Manufacturing Science and Technology at Bristol-Myers Squibb (BMS), a publicly traded biopharmaceutical company. Prior to BMS, Dr. Gadam served as Vice President of Global Cell Therapy Manufacturing Science and Technology at Juno Therapeutics, a Celgene company, until its acquisition by BMS in November 2019. From March 2006 to June 2018, Dr. Gadam worked at Genentech, Inc., a privately held biotechnology company and member of the Roche Group, in various global leadership roles in Biologics Technical Development and Operations. Dr. Gadam received a Ph.D. in Chemical Engineering from Rensselaer Polytechnic Institute, a M.S. in Chemical Engineering from West Virginia University and a Bachelor of Chemical Engineering from the Department of Chemical Technology at the University of Bombay.

Ginna Laport, M.D. has served as our Chief Medical Officer since October 2023. Prior to joining our company, Dr. Laport served as the Vice President, Global Head of Lymphoma/CLL Clinical Development at Genentech, Inc., a biotechnology company, from January 2020 to October 2023. Prior to Genentech, from September 2018 to October 2019, Dr. Laport served as the Chief Medical Officer for Tempest Therapeutics, Inc., a clinical-stage oncology company. Prior to Tempest, Dr. Laport served as Vice President of Clinical Development for Corvus Pharmaceuticals, Inc., a biopharmaceutical company, from October 2015 to September 2018. Dr. Laport earned an M.D. from the University of Texas Health Science Center at Houston and completed a residency in internal medicine and a fellowship in hematology/oncology at the University of Chicago Medicine. She obtained a B.A. in Psychology from Baylor University.

Non-employee directors

John Orwin, MBA has served as chairperson of our board of directors since September 2022. Since April 2018, Mr. Orwin has served as President and Chief Executive Officer of Atreca, Inc., a publicly traded biopharmaceutical company. From 2013 to 2017, Mr. Orwin served as President and Chief Executive Officer of Relypsa, Inc., a biopharmaceutical company acquired by Galenica AG in 2016. Prior to that, from 2010 to 2011, Mr. Orwin served as President and Chief Executive Officer of Affymax, Inc., a publicly traded biotechnology company. From 2005 to 2010, Mr. Orwin served as Vice President, and later Senior Vice President, of the BioOncology Business Unit at Genentech, Inc., a privately held biotechnology company and member of the Roche Group. Mr. Orwin currently serves as a member of the board of directors of Atreca, Inc., Travere Therapeutics, Inc. and Seagen, Inc. Mr. Orwin previously served as a member of the board of directors of Affymax. Inc., Array BioPharma, Inc., Relypsa Inc. and NeurogesX, Inc. Mr. Orwin received a B.A. in Economics from Rutgers University and an M.B.A. from the New York University Leonard M. Stern School of Business. We believe that Mr. Orwin is qualified to serve as a member of our board of directors due to his education and extensive experience as an executive officer in the biopharmaceutical and biotechnology industries.

Abraham Bassan has served as a member of our board of directors since February 2021. Since April 2021, Mr. Bassan has served as a Principal at Samsara BioCapital, a privately held life science investment firm. From July 2017 to April 2021, Mr. Bassan served as a Vice President at Samsara BioCapital. From December 2014 to July 2017, Mr. Bassan served as Director of Program Biology at Revolution Medicines, a then privately held

oncology company. Prior to that, from 2010 to 2012, Mr. Bassan served as Associate Director of Program Management at bluebird bio, Inc., a publicly traded biotechnology company. Mr. Bassan currently serves as a member of the board of directors at Graphite Bio, Inc. Mr. Bassan received an A.B. in Molecular Biology from Princeton University and an M.S. in Developmental Biology from Stanford University. We believe that Mr. Bassan is qualified to serve as a member of our board of directors due to his education and his experience in the life sciences and oncology fields, particularly with respect to operating and investing in cell therapy companies.

Reid Huber, Ph.D. has served as a member of our board of directors since March 2023. Since December 2018, Dr. Huber has served as a Partner at Third Rock Ventures, LLC, a privately held early-stage life sciences venture capital firm. Prior to Third Rock, from 2002 to December 2018, Dr. Huber worked at Incyte Corporation, a publicly traded pharmaceutical company, where he served as Executive Vice President, Chief Scientific Officer, from 2011 to December 2018. Before joining Incyte, from 1997 to 2002, Dr. Huber held scientific research positions at DuPont Pharmaceuticals Company and BMS. Dr. Huber serves on the board of directors of Tango Therapeutics Inc. Dr. Huber received his Ph.D. in Molecular Genetics from the Washington University School of Medicine and held pre- and post-doctoral fellowships at the National Institutes of Health. We believe that Dr. Huber is qualified to serve on our board of directors due to his educational background and extensive experience in the biopharmaceutical industry.

David C. Lubner, M.S., C.P.A. has served as a member of our board of directors since July 2023. From January 2016 until June 2020, Mr. Lubner served as Executive Vice President and Chief Financial Officer of Ra Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company, acquired by UCB S.A. in April 2020. Prior to joining Ra Pharmaceuticals, Mr. Lubner served as Chief Financial Officer of Tetraphase Pharmaceuticals, Inc., a biotechnology company, from 2006 through 2016, and as Chief Financial Officer of PharMetrics Inc., a patient-based pharmacy and medical claims data informatics company, from 1999 until 2006. Prior to joining PharMetrics, Mr. Lubner served as Vice President and Chief Financial Officer of ProScript, Inc. from 1996 to 1999. Mr. Lubner currently serves on the board of directors of a number of publicly traded biotechnology companies, including Arcellx, Inc., Dyne Therapeutics, Inc., POINT Biopharma, Inc. and Vor Biopharma, Inc. He was previously a member of the board of directors of Gemini Therapeutics, Inc., which merged with Disc Medicine, Inc. in December 2022, Nightstar Therapeutics plc, which was acquired by Biogen Inc. in June 2019, and Therapeutics Acquisition Corp., a blank check company focused on the healthcare industry, sponsored by RA Capital, Boston, MA. Mr. Lubner is a Certified Public Accountant in the Commonwealth of Massachusetts. Mr. Lubner received his B.S. in Business Administration from Northeastern University and M.S. in Taxation from Bentley University. We believe that Mr. Lubner is qualified to serve on our board of directors because of his extensive experience serving in senior level financial positions and his experience with biopharmaceutical companies.

Crystal Mackall, M.D. has served on our board of directors since January 2021. Since January 2016, Dr. Mackall has served as Professor of Pediatrics and Medicine at Stanford University School of Medicine. She is also Director of the Stanford Center for Cancer Cell Therapy and Director of the Parker Institute for Cancer Immunotherapy at Stanford. Prior to her time at Stanford, from 2008 to 2015, Dr. Mackall served as Chief of the Pediatric Oncology Branch at the National Cancer Institute. For more than two decades, she has led an internationally recognized translational research program focused on basic immunology and cancer immunotherapy. Dr. Mackall has also served on numerous biotechnology and pharmaceutical company scientific advisory boards and previously co-founded Lyell Immunopharma, Inc., and Link Cell Therapies Inc., which are developing CAR T cell therapies Dr. Mackall received an M.D. from Northeastern Ohio Universities College of Medicine and completed a residency in pediatrics and internal medicine at Children’s Hospital Medical Center of Akron and a fellowship in pediatric hematology/oncology at the the National Cancer Institute, an Institute of the National Institutes of Health. She received a B.S. in Natural Sciences from the University of

Akron. We believe that Dr. Mackall is qualified to serve on our board of directors due to her education and extensive experience in the biotechnology, pharmaceutical and oncology sectors.

Krishnan Viswanadhan, Pharm.D. has served on our board of directors since October 2022. Since July 2021, Dr. Viswanadhan has served as President and Chief Operating Officer at Be Biopharma Inc., a privately held biopharmaceutical company. Prior to Be Biopharma, from August 2019 to July 2021, Dr. Viswanadhan was Senior Vice President, Global Cell Therapy Franchise Lead at BMS, a publicly traded biopharmaceutical company. Prior to BMS, from January 2018 to August 2019, Dr. Viswanadhan was Vice President, Business Development and Global Alliances at Celgene Corporation, a pharmaceutical oncology company that was acquired by BMS in November 2019. Dr. Viswanadhan currently serves on the board of directors of JW Therapeutics, a cell therapy company in China. Dr. Viswanadhan is a registered Pharmacist and received a Pharm.D from Rutgers University, an M.B.A. from Cornell University and a B.S. in Pharmacy and Economics from Rutgers University. We believe that Dr. Viswanadhan is qualified to serve on our board due to his education and extensive experience as a biopharmaceutical executive.

Key employees

Halley Gilbert, J.D. has served as our Chief Legal Officer since since August 2023. Prior to joining our company, from August 2021 to May 2022, Ms. Gilbert served as Chief Legal Officer for NeoGenomics Laboratories, Inc., a global cancer genomics and informatics company. Prior to NeoGenomics, from June 2020 to August 2021, Ms. Gilbert was Chief Operating Officer for Invivyd, Inc. (formerly Adagio Therapeutics, Inc.), a biopharmaceutical company. Prior to Invivyd, from February 2008 to February 2020, Ms. Gilbert worked at Ironwood Pharmaceuticals, Inc., a gastrointestinal healthcare company, in roles of increasing responsibility, including Chief Administrative Officer & SVP of Corporate Development, and Chief Legal Officer. Ms. Gilbert currently serves on the board of directors of CytomX Therapeutics, Inc., Vaxcyte, Inc. and Arcutis Biotherapeutics, Inc. Ms. Gilbert earned a J.D. from Northwestern University Pritzker School of Law and a B.A. from Tufts University.

Michael Ports, Ph.D. has served as our Chief Scientific Officer since August 2023. Prior to joining our company, Dr. Ports worked at The Janssen Pharmaceuticals Companies of Johnson & Johnson, serving as Vice President and Head of Cell Therapy Discovery from February 2022 to August 2023 and Senior Director, Cell Therapy Research from April 2020 to February 2022. Prior to Janssen, from May 2015 to April 2020, Dr. Ports worked at Juno Therapeutics, Inc. (acquired by Celgene Corporation) and Celgene Corporation (acquired by Bristol-Myers Squibb Company), where he served in roles of increasing responsibility. Dr. Ports served as a Postdoctoral Fellow at the Netherlands Cancer Institute and Fred Hutchinson Cancer Research Center. Dr. Ports obtained a Ph.D. in Cancer Biology from the University of Arizona and a B.S. in Molecular, Cellular and Developmental Biology from the University of California, Santa Barbara.

Family relationships

There are no family relationships among any of our executive officers or directors.

Board structure and composition

Director independence

Our board of directors currently consists of seven members with one member expected to resign prior to the effectiveness of the registration statement of which this prospectus is a part. Our board of directors has determined that all of our directors, other than Ms. Chapman, Mr. Bassan and Dr. Mackall, qualify as

independent directors in accordance with the Nasdaq Stock Market LLC (Nasdaq) Marketplace Rules (the Nasdaq Listing Rules). Ms. Chapman and Dr. Mackall are not considered independent by virtue of their positions as Chief Executive officer and consultant, respectively, of the company. Mr. Bassan is not considered independent by virtue of his former position as President of the company. Under the Nasdaq Listing Rules, the definition of independence includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by the Nasdaq Listing Rules, our board of directors has made a subjective determination as to each independent director that no relationships exist that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's relationships as they may relate to us and our management.

Classified board of directors

In accordance with our amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I directors will be Krishnan Viswanadhan and Reid Huber, and their terms will expire at the annual meeting of stockholders to be held in 2024;
- The Class II directors will be Abraham Bassan and David Lubner, and their terms will expire at the annual meeting of stockholders to be held in 2025; and
- The Class III directors will be John Orwin and Gina Chapman, and their terms will expire at the annual meeting of stockholders to be held in 2026.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Voting arrangements

The election of the members of our board of directors is currently governed by the voting agreement that we entered into with certain holders of our common stock and convertible preferred stock and the related provisions of our amended and restated certificate of incorporation. Pursuant to our voting agreement and amended and restated certificate of incorporation, our current directors were elected as follows:

- Mr. Bassan was elected as the designee of Samsara BioCapital, L.P.;
- Cassandra Gianna Luca, Ph.D., who resigned from our board of directors in October 2023, was elected as the designee of Perceptive Xontogeny Venture Fund II, LP;
- Dr. Huber was elected as the designee of Third Rock Ventures V, L.P.;
- Heath Lukatch, Ph.D., who resigned from our board of directors in October 2023, was elected as the designee of Red Tree Venture Fund, L.P.;

- Dr. Huber and Dr. Luca were elected and designated by the holders of a majority of our Series A-1 convertible preferred stock;
- Mr. Bassan and Dr. Lukatch were elected and designated by the holders of a majority of our Series Seed convertible preferred stock;
- Dr. Mackall was elected and designated by the holders of a majority of our common stock held by the founders, together with their respective affiliates;
- Ms. Chapman was elected and designated as our then serving and current Chief Executive Officer; and
- Mr. Orwin and Dr. Viswanadhan were elected and designated by the holders of a majority of our common stock and convertible preferred stock.

Our voting agreement will terminate and the provisions of our current amended and restated certificate of incorporation by which our directors were elected will be amended and restated in connection with this offering. After this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the completion of this offering. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier death, resignation or removal.

Leadership structure of the board

Our amended and restated bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of Chairperson of the board of directors and Chief Executive Officer. Mr. Orwin currently serves as the Chairperson of the board of directors.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of board in risk oversight process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. While our board of directors is responsible for monitoring and assessing strategic risk exposure, our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also approves or disapproves any related-party transactions. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines.

Board committees

Our board of directors has three standing committees: the audit committee, the compensation committee and the nominating and governance committee. Each committee is governed by a charter that will be available on our website following completion of this offering.

Audit committee

The members of our audit committee consist of David Lubner, Krishnan Viswanadhan and John Orwin. David Lubner is the chairperson of our audit committee. The composition of our audit committee meets the requirements for independence under the current Nasdaq Listing Rules and Rule 10A-3 of the Exchange Act. Each member of our audit committee is financially literate. In addition, our board of directors has determined that David Lubner is an “audit committee financial expert” within the meaning of the SEC rules. This designation does not impose on such directors any duties, obligations, or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- appointing, retaining, compensating and overseeing the work of our independent registered public accounting firm;
- assessing the independence and performance of the independent registered public accounting firm;
- reviewing with our independent registered public accounting firm the scope and results of the firm’s annual audit of our financial statements;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the financial statements that we will file with the SEC;
- pre-approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- reviewing policies and practices related to risk assessment and management;
- reviewing our accounting and financial reporting policies and practices and accounting controls, as well as compliance with legal and regulatory requirements;
- reviewing, overseeing, approving, or disapproving any related-person and related-party transactions;
- reviewing with our management the scope and results of management’s evaluation of our disclosure controls and procedures and management’s assessment of our internal control over financial reporting, including the related certifications to be included in the periodic reports we will file with the SEC; and
- establishing procedures for the confidential anonymous submission of concerns regarding questionable accounting, internal controls, or auditing matters, or other ethics or compliance issues.

Compensation committee

The members of our compensation committee consist of John Orwin, David Lubner and Reid Huber. John Orwin is the chairperson of our compensation committee. Each of John Orwin, David Lubner and Reid Huber is a

non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaq Listing Rules. Our compensation committee is responsible for, among other things:

- reviewing and approving the compensation of our executive officers, including reviewing and approving corporate goals and objectives with respect to compensation;
- authority to act as an administrator of our equity incentive plans;
- reviewing and approving, or making recommendations to our board of directors with respect to, incentive compensation and equity plans;
- reviewing and recommending that our board of directors approve the compensation for our non-employee board members; and
- establishing and reviewing general policies relating to compensation and benefits of our employees.

Nominating and governance committee

The members of our nominating and governance committee consist of Krishnan Viswanadhan and Reid Huber. Krishnan Viswanadhan is the chairperson of our nominating and governance committee. Krishnan Viswanadhan and Reid Huber meet the requirements for independence under the current Nasdaq Listing Rules. Our nominating and governance committee is responsible for, among other things:

- identifying and recommending candidates for membership on our board of directors, including the consideration of nominees submitted by stockholders, and on each of the board's committees;
- reviewing and recommending our corporate governance guidelines and policies;
- reviewing proposed waivers of the code of business conduct and ethics for directors and executive officers;
- overseeing the process of evaluating the performance of our board of directors; and
- assisting our board of directors on corporate governance matters.

Code of business conduct and ethics

In connection with this offering, our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our code of business conduct and ethics will be posted on the investor relations section of our website. We intend to disclose future amendments to our code of business conduct and ethics, or any waivers of such code, on our website or in public filings.

Compensation committee interlocks and insider participation

None of our executive officers has served as a member of a compensation committee (or if no committee performs that function, the board of directors) of any other entity that has an executive officer serving as a member of our board of directors.

Director compensation

For the year ended December 31, 2022, we did not have a formalized non-employee director compensation program, but we provided compensation to our non-employee directors who are not affiliated with our investors in accordance with their individual agreements.

In connection with the commencement of their service as directors, we entered into offer letters with Mr. Orwin and Dr. Viswanadhan that provide for annual cash fees of $45,000 and $30,000, respectively, which were prorated for their period of service in 2022. Each offer letter also provides for an initial equity grant, as described below, reimbursement of business expenses, and includes a perpetual confidentiality covenant and an assignment of inventions provision.

On October 7, 2022, in accordance with the terms of his offer letter, we granted Mr. Orwin an option to purchase 15,865 shares of our common stock with an exercise price per share of $1.09, which our board of directors determined equaled fair market value on the date of grant. The option vests as to 1/48th of the number of shares subject to the option on the day of each month commencing in September 2022.

On October 27, 2022, in accordance with the terms of his offer letter, we granted Dr. Viswanadhan an option to purchase 3,173 shares of our common stock with an exercise price per share of $1.09, which our board of directors determined equaled fair market value on the date of grant. The option vests as to 1/48th of the number of shares subject to the option on the day of each month commencing in October 2022.

During 2022, Dr. Mackall received cash compensation for consulting services provided to the Company under her consulting agreement with the Company, entered into in February 2021, pursuant to which she provides advice, assistance and other expert consulting services as mutually agreed for a minimum of 192 hours per year, particularly regarding matters relating to CAR T cell therapy of B-cell malignancies, bi-specific CARs, manufacturing, clinical trial design, CAR toxicities and other scientific matters concerning CAR T cells as they arise. The consulting agreement provides for cash consulting fees at a rate of $160,000 per year, reimbursement of business expenses, and includes a perpetual confidentiality covenant, an assignment of inventions provision and non-competition and employee and customer non-solicitation covenants that apply during the term of the agreement. The term of the consulting agreement will end on February 17, 2025, subject to earlier termination by either party and may be extended by mutual agreement.

Director compensation table

The following table sets forth information concerning the compensation earned by our non-employee directors during the year ended December 31, 2022.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[1]	Option Awards ($)[2]	All Other Compensation ($)[3]	Total ($)
John Orwin	16,151	—	12,836	—	28,986
Abraham Bassan	—	—	—	—	—
Cassandra Gianna Luca[4]	—	—	—	—	—
Reid Huber, Ph.D.	—	—	—	—	—
Crystal Mackall, M.D.	—	121,023	—	160,000	281,023
Krishnan Viswanadhan, Pharm.D.	6,575	—	2,565	—	9,140

(1) In April 2022, the performance vesting conditions applicable to 112,761 shares of restricted stock held by Dr. Mackall were removed. The amount reported represents the incremental fair value, reported as of the modification date, of that modification, computed in accordance with the Financial Accounting and Standards Board (FASB) Accounting Standards Codification Topic 718. The assumptions used in calculating the modification date fair value are described in Note 9 to our audited financial statements included elsewhere in this prospectus.

(2) The amounts reported represent the grant date fair value of option awards granted to our non-employee directors during the year ended December 31, 2022 as computed in accordance with FASB ASC 718, rather than amounts paid to or realized by the individual. The assumptions used in calculating the grant date fair value of the awards are described in Note 9 to our audited financial statements included elsewhere in this prospectus. As of December 31, 2022, Mr. Orwin and Dr. Viswanadhan held options to purchase 15,865 and 3,173 shares of our common stock, respectively, and Dr. Mackall held 172,274 shares of restricted stock. None of our other non-employee directors held option or stock awards.

(3) The amount reported represents consulting fees paid to Dr. Mackall for services provided to the Company during 2022.

(4) Dr. Luca resigned from our board of directors in October 2023.

We have adopted a compensation program for our non-employee directors to be effective on the consummation of this offering.

Executive compensation

The following is a discussion of compensation arrangements of our named executive officers (NEOs). This discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

We seek to ensure the total compensation paid to our executive officers is reasonable and competitive. Compensation of our executives is structured around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Our NEOs for 2022 were as follows:

- Gina Chapman, our President and Chief Executive Officer;
- Shishir Gadam, Ph.D., our Chief Technology Officer; and
- Gregg Fine, M.D., our former Chief Medical Officer.

Ms. Chapman has served as our President and Chief Executive Officer since May 2, 2022. Dr. Gadam has served as our Chief Technology Officer since January 17, 2022. Dr. Fine served as our Chief Medical Officer through September 1, 2023 and currently serves as a Strategic Advisor to us.

2022 summary compensation table

The following table sets forth total compensation paid to our NEOs for the year ended December 31, 2022.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock awards ($)[2]	Non-equity incentive plan compensation ($)[3]	All other compensation ($)	Total ($)
Gina Chapman *Chief Executive Officer*	2022	333,333	50,000	69,928	202,500	2,850	658,612
Shishir Gadam, Ph.D. *Chief Technical Officer*	2022	383,333	45,000	19,160	245,700	—	693,193
Gregg Fine, M.D. *Chief Medical Officer*	2022	404,034	50,000	23,394	164,064	—	641,492

(1) The amounts reported represent bonuses paid to our NEOs in connection with their commencement of employment.

(2) The amounts reported represent the grant date fair value of restricted stock awards granted to our NEOs during the year ended December 31, 2022 as computed in accordance with FASB Accounting Standards Codification Topic 718, rather than amounts paid to or realized by the individual. The assumptions used in calculating the grant date fair value of the awards are described in Note 10 to our audited financial statements included in this prospectus.

(3) The amounts reported represent the annual performance-based bonuses earned by our NEOs based on the achievement of certain corporate and individual performance objectives during 2022. These amounts were paid to our NEOs in early 2023.

Narrative to summary compensation table

2022 salaries

Our NEOs each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

For 2022, Drs. Gadam and Fine had annual base salaries of $400,000 and $405,096, respectively. Ms. Chapman's annual base salary was established at $500,000 in connection with her appointment as our Chief Executive Officer in May 2022.

In February 2023, Ms. Chapman's, Dr. Gadam's and Dr. Fine's annual base salaries were increased to $525,000, $418,000 and $418,262, respectively.

In connection with Dr. Fine's transition to the part-time position of Strategic Advisor in September 2023, Dr. Fine's base salary was reduced to $7,000 per week.

Our board of directors and compensation committee may adjust base salaries from time to time in their discretion.

2022 bonuses

We maintain an annual performance-based cash bonus program in which each of our NEOs participated in 2022. Each NEO's target bonus is expressed as a percentage of their annual base salary which can be achieved by meeting company and individual goals at target level. The 2022 annual bonus for Dr. Gadam was targeted at 35% of his base salary and for Dr. Fine was targeted at 30% of his base salary. Ms. Chapman's 2022 annual bonus was established at 45% of her base salary in connection with her appointment as our Chief Executive Officer.

In February 2023, our board of directors, upon recommendation of the compensation committee, determined achievement under our 2022 annual bonus program and awarded bonuses to Ms. Chapman, Dr. Gadam and Dr. Fine based on corporate and individual performance in the amount of $202,500, $245,700 and $164,064, respectively.

In connection with Ms. Chapman's appointment as our Chief Executive Officer in May 2022, we agreed to assist Ms. Chapman with her transition to us by awarding her a transition bonus of $300,000, payable in six equal biannual installments of $50,000 commencing shortly after her commencement of employment with us, with each installment subject to her continued employment through the date of payment.

In connection with Dr. Gadam's commencement of employment with us as our Chief Technology Officer in January 2022, we paid Dr. Gadam a signing bonus of $45,000 shortly following his commencement of employment with us and he was eligible to earn an additional payment of $45,000 within 30 days following the first anniversary of his commencement of employment with us and $70,000 upon the initiation of a registrational trial for our lead program, in each case, subject to Dr. Gadam's continued employment with us through the applicable payment date.

In connection with Dr. Fine's commencement of employment with us as our Chief Medical Officer in September 2021, we paid Dr. Fine a transition bonus of $50,000 shortly following his commencement of employment with us and an additional payment of $50,000 following the first anniversary of his commencement of employment with us.

Our board of directors and compensation committee may adjust annual bonuses or award discretionary bonuses from time to time.

Equity-based compensation

In connection with Ms. Chapman's commencement of employment as our Chief Executive Officer, on June 24, 2022, we granted Ms. Chapman an award providing her the right to purchase 103,905 restricted shares of our common stock (restricted stock) for $1.09 per share, which our board of directors determined equaled fair market value of our common stock on the date of grant, subject to a right of repurchase at the original purchase price in connection with certain terminations of Ms. Chapman's employment. Ms. Chapman purchased the shares underlying the award on June 29, 2022. The restricted stock vests, and the right of repurchase to lapses, as to 25% of the shares on May 2, 2023 and as to 1/48th of the original number of shares each month

thereafter, subject to Ms. Chapman's continued employment with us through the applicable vesting date. Vesting is subject to acceleration upon certain terminations of Ms. Chapman's employment, as described below under the heading "—Executive compensation arrangements—Gina Chapman."

On June 24, 2022, we granted Dr. Gadam an award providing him the right to purchase 29,480 shares of restricted stock for $1.09 per share, which our board of directors determined equaled fair market value of our common stock on the date of grant, subject to a right of repurchase at the original purchase price upon certain terminations of Dr. Gadam's employment. Dr. Gadam purchased the shares underlying the award on June 30, 2022. The restricted stock vests, and the right of repurchase to lapses, as to 25% of the shares subject to the award on January 17, 2023 and as to 1/48th of the original number of shares each month thereafter, subject to Dr. Gadam's continued employment with us through the applicable vesting date. Vesting is subject to acceleration upon certain terminations of Dr. Gadam's employment, as described below under the heading "—Executive compensation arrangements—Shishir Gadam, Ph.D." On June 24, 2022, we granted Dr. Fine an award providing him the right to purchase 29,054 shares of restricted stock for $1.09 per share, which our board of directors determined equaled fair market value of our common stock on the date of grant, subject to a right of repurchase at the original purchase price upon certain terminations of Dr. Fine's employment. Dr. Fine purchased the shares underlying the award on July 14, 2022. The restricted stock vests, and the right of repurchase lapses, as to 25% of the shares on September 30, 2023 and as to 1/48th of the original number of shares each month thereafter, subject to Dr. Fine's continued employment with us through the applicable vesting date. Vesting is subject to acceleration upon certain terminations of Dr. Fine's employment, as described below under the heading "—Executive compensation arrangements—Gregg Fine, M.D."

Also on June 24, 2022, we granted Dr. Fine an additional award providing him the right to purchase 8,435 shares of restricted stock for $1.09 per share, which our board of directors determined equaled fair market value of our common stock on the date of grant, subject to a right of repurchase at the original purchase price upon certain terminations of Dr. Fine's employment. Dr. Fine purchased the shares underlying the award on July 14, 2022. The restricted stock vests, and the right of repurchase lapses, as to 20% of the shares on September 30, 2023 and as to 1/60th of the original number of shares each month thereafter, subject to Dr. Fine's continued employment with us through the applicable vesting date and subject to accelerated vesting upon the attainment of certain clinical milestone achievements. Vesting is subject to acceleration upon certain terminations of Dr. Fine's employment, as described below under the heading "—Executive compensation arrangements—Gregg Fine, M.D."

On April 21, 2023, we granted each of our NEOs an option to purchase shares of our common stock with an exercise price per share of $5.03, which our board of directors determined equaled fair market value of our common stock on the date of grant. Each option includes three separate vesting tranches. Each tranche vests as to 25% of the shares underlying the tranche on the first anniversary of the vesting commencement date for the tranche and as to 1/48th of the shares underlying the tranche each month thereafter, subject to continued employment through the applicable vesting date. Vesting is subject to acceleration upon certain terminations of the NEOs' employment, as described below under the heading "—Executive compensation arrangements." The vesting commencement date for the first, second and third tranche coincides with the closing of the first, second and third tranche of our Series A-1 preferred stock financing. The number of shares underlying each tranche for each named executive officer are as follows:

Named Executive Officer	Tranche 1	Tranche 2	Tranche 3	Total
Gina Chapman	559,656	169,097	314,906	1,043,659
Shishir Gadam, Ph.D.	116,503	37,201	69,279	222,983
Gregg Fine, M.D.	99,096	66,064	123,870	289,030

Other elements of compensation

Retirement savings and health and welfare benefits

We currently maintain a 401(k) retirement savings plan for our employees, including our NEOs, who satisfy certain eligibility requirements. Our NEOs are eligible to participate in the 401(k) plan on the same terms as other full-time employees.

All of our full-time employees, including our NEOs, are eligible to participate in our health and welfare plans, including health, dental and vision benefits; medical and dependent care flexible spending accounts; short-term and long-term disability insurance; and life and AD&D insurance.

Perquisites and other personal benefits

We did not provide any perquisites to our NEOs during 2022 other than reimbursing Ms. Chapman for legal fees incurred in connection with negotiating her employment offer letter in connection with her appointment as our Chief Executive Officer.

Our compensation committee may from time to time approve perquisites in the future when our compensation committee determines that they are necessary or advisable to fairly compensate or incentivize our employees.

Outstanding equity awards at 2022 year end

The following table lists all outstanding equity awards held by our NEOs as of December 31, 2022.

		Stock Awards	
Name	Vesting Commencement Date[1]	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)[2]
Gina Chapman	5/5/2022	103,905	112,788
Shishir Gadam, Ph.D.	1/17/2022	29,480	32,000
Gregg Fine, M.D.	9/30/2021	19,974	21,682
	9/30/2021[3]	6,326	6,867

(1) Except as otherwise noted, each award of restricted stock vests, and the right of repurchase thereon lapses, as to 25% of the shares comprising the award on the first anniversary of the vesting commencement date and as to 1/48th of the initial number of shares comprising the award monthly thereafter, subject to accelerated vesting as set forth in the named executive officer's offer letter. Unvested shares may be repurchased for the original purchase price in the event of a termination of employment.

(2) Values reported based on $1.09 per share, which our board of directors determined equaled the fair market value of a share of our common stock as of December 31, 2022.

(3) Award of restricted stock vests, and the right of repurchase thereon lapses, as to 20% of the shares comprising the award on the first anniversary of the vesting commencement date and as to 1/60th of the initial number of shares comprising the award monthly thereafter, subject to accelerated vesting in the event certain clinical milestones are achieved and as set forth in Dr. Fine's offer letter. Unvested shares may be repurchased for the original purchase price in the event of a termination of employment.

Executive compensation arrangements

We have entered into offer letters and proprietary information and invention assignment agreements with each of our NEOs. Each offer letter sets forth the title, base salary, target bonus opportunity and initial equity awards for the executive. In addition, the offer letters provide for certain NEOs to receive transition bonuses, relocation

assistance and guaranteed equity awards and for each NEO to receive severance in the event the executive's employment with us is terminated by us without cause or by the executive for good reason, each as defined in the applicable offer letter, subject to each executive's continued compliance with additional terms as set out in each applicable offer letter. Each executive must also provide a general release of claims in order to receive severance benefits.

Gina Chapman

We entered into an offer letter with Ms. Chapman in March 2022 that provided for her to be appointed our Chief Executive Officer on May 2, 2022. Ms. Chapman's offer letter provides for her to be paid an annual base salary of $500,000, subject to increase, and an annual bonus targeted at 45% of her annual base salary, subject to pro-ration based on her partial year of service in 2022. Under the offer letter, we agreed to assist Ms. Chapman with her transition to us by awarding her a transition bonus of $300,000, payable in six equal biannual installments, with the first installment paid shortly after her commencement of employment with us. The offer letter also provided for Ms. Chapman to be granted the right to be issued 103,905 shares of restricted stock for a purchase price equal to fair market value on the date of issuance (the Initial Chapman Award), which our board of directors determined equaled $1.09 per share when granted on June 24, 2022. Any unvested shares of restricted stock are subject to repurchase by us at the original purchase price in the event of a termination of employment. The restricted stock vests, and the right of repurchase thereon lapses, as to 25% of the shares on the first anniversary of Ms. Chapman's commencement of employment, which was May 2, 2022, and as to 1/48th of the initial number of shares monthly thereafter, subject to Ms. Chapman's continued employment. The offer letter also provided for Ms. Chapman to be granted an additional equity award covering a number of shares necessary to provide Ms. Chapman with shares or rights to shares covering an aggregate of 5% of our fully diluted capitalization following the completion of our Series A convertible preferred stock financing. The offer letter also provided for Ms. Chapman to receive up to $10,000 in reimbursement of legal fees incurred in negotiating the offer letter.

In addition, Ms. Chapman's offer letter provides that in the event her employment with us is terminated at any time other than following the occurrence of a sale event (as defined in the offer letter) by us other than for cause (as defined in the offer letter), death or disability or if she resigns her employment for good reason (as defined in her offer letter), Ms. Chapman is entitled to receive: 12 months of continued base salary, a lump sum payment of any earned and unpaid bonus for the prior year and target bonus opportunity for the year in which her termination occurs, a lump sum payment of any unpaid portion of the transition bonus, a monthly payment for continued healthcare coverage for up to 12 months, accelerated vesting of 25% of the unvested equity awards with time-based vesting (any awards subject to solely performance-based vesting shall be treated as specified in the applicable award agreement) and extended exercisability for any stock options until the earlier of 3 months following Ms. Chapman's date of termination or the original expiration date applicable to such options. In the event such a termination or resignation occurs during the 12-month period commencing on a sale event, Ms. Chapman is entitled to the same payments and benefits described above except that cash severance will be paid in a single cash lump sum and the vesting of all unvested equity awards with time-based vesting will be accelerated. All severance payments and benefits are contingent on Ms. Chapman timely delivering a general release of claims against us.

On February 9, 2023, we entered into an amendment to Ms. Chapman's offer letter that clarified the anti-dilution protection provided in the original offer letter. Under the amendment, Ms. Chapman became entitled to the grant of options to purchase 1,043,659 shares of our common stock that was designed to provide Ms. Chapman with shares and options to purchase shares that, when combined with the Initial Chapman Award, constitute 5% of our fully diluted capitalization as determined on a pro-forma basis assuming that $200 million of convertible preferred stock would be sold in our Series A convertible preferred stock financing.

Our board of directors granted the option on April 21, 2023 with an exercise price per share of $5.03, which our board of directors determined equaled fair market value on the date of grant. The option vests in three tranches, each of which correlates to a closing of our Series A convertible preferred stock financing, with the number of shares subject to each tranche intended to provide Ms. Chapman with shares and options to purchase shares together constituting 5% of our fully diluted capitalization as of immediately following the applicable closing. The number of shares underlying each tranche is 559,656, 169,097 and 314,906 for tranches 1, 2 and 3, respectively. Each tranche commences vesting on the closing of the related tranche of the Series A convertible preferred stock financing, which was February 9, 2023 for tranche 1, July 7, 2023 for tranche 2 and October 27, 2023 for tranche 3. Each tranche vests as to 25% of the shares underlying the tranche on the first anniversary of the applicable vesting commencement date and as to 1/48th of the shares underlying the tranche each month thereafter, subject to Ms. Chapman's continued service to us.

Shishir Gadam, Ph.D.

We entered into an offer letter with Dr. Gadam in October 2021 that provided for him to be employed by us as our Chief Technology Officer commencing on January 17, 2022. Dr. Gadam's offer letter provides for him to be paid an annual base salary of $400,000, subject to increase, and an annual bonus targeted at 35% of his annual base salary, subject to pro-ration in 2022. Under the offer letter, we also agreed to pay Dr. Gadam a sign-on bonus of $45,000 within 30 days following his commencement of employment with us, $45,000 within 30 days following the first anniversary of his commencement of employment with us and $70,000 upon the initiation of a registrational trial for our lead program. The offer letter also provided for Dr. Gadam to be granted the right to be issued 29,480 shares of restricted stock for a purchase price equal to fair market value on the date of issuance (the Initial Gadam Award), which our board of directors determined equaled $1.09 per share when granted on June 24, 2022. Any unvested shares of restricted stock are subject to repurchase by us at the original purchase price in the event of a termination of employment. The restricted stock vests, and the right of repurchase thereon lapses, as to 25% of the shares on the first anniversary of Dr. Gadam's commencement of employment, which was January 17, 2022, and as to 1/48th of the initial number of shares monthly thereafter, subject to Dr. Gadam's continued employment.

In addition, Dr. Gadam's offer letter provides that in the event his employment with us is terminated at any time other than following the occurrence of a sale event (as defined in the offer letter) by us other than for cause (as defined in the offer letter), death or disability or Dr. Gadam resigns for good reason, Dr. Gadam is entitled to receive: 9 months of continued base salary, monthly payments for continued healthcare coverage for up to 9 months, accelerated vesting of all unvested equity awards that would have vested in the 9-month period immediately following his termination of employment, a lump sum payment of any unpaid portion of his signing bonus and payment of any earned but unpaid annual bonus. In the event such a termination or resignation occurs during the 12-month period commencing on a sale event, Dr. Gadam is entitled to receive: a lump sum payment of 12 months of his base salary, a lump sum payment of any earned and unpaid bonus for the prior year and target bonus opportunity for the year in which his termination occurs, a lump sum payment of any unpaid portion of the signing bonus, monthly payments for continued healthcare coverage for up to 12 months, accelerated vesting of all unvested equity awards with time-based vesting (any awards subject to solely performance-based vesting shall be treated as specified in the applicable award agreement) and extended exercisability for any stock options until the earlier of 3 months following Dr. Gadam's date of termination or the original expiration date applicable to such options. All severance payments and benefits are contingent on Dr. Gadam timely delivering a general release of claims against us.

On February 9, 2023, we entered into an amendment to Dr. Gadam's offer letter that provided for the grant of an option to purchase 222,983 shares of our common stock that was designed to provide Dr. Gadam with shares and options to purchase shares that, when combined with the Initial Gadam Award, constitute 1.1% of our fully diluted capitalization as determined on a pro-forma basis assuming that $200 million of convertible preferred

stock would be sold in our Series A convertible preferred stock financing. Our board of directors granted the option on April 21, 2023 with an exercise price per share of $5.03, which our board of directors determined equaled fair market value on the date of grant. The option vests in three tranches, each of which correlates to a closing of our Series A convertible preferred stock financing, with the number of shares subject to each tranche intended to provide Dr. Gadam with shares and options to purchase shares together constituting 1.1% of our fully diluted capitalization as of immediately following the applicable closing. The number of shares underlying each tranche is 116,503, 37,201 and 69,279 for tranches 1, 2 and 3, respectively. Each tranche commences vesting on the closing of the related tranche of the Series A convertible preferred stock financing, which was February 9, 2023 for tranche 1, July 7, 2023 for tranche 2 and October 27, 2023 for tranche 3. Each tranche vests as to 25% of the shares underlying the tranche on the first anniversary of the applicable vesting commencement date and as to 1/48th of the shares underlying the tranche each month thereafter, subject to Dr. Gadam's continued service to us.

Gregg Fine, M.D.

We entered into an offer letter with Dr. Fine in August 2021 that provided for him to be employed by us as our Chief Medical Officer commencing on September 30, 2021. Dr. Fine's offer letter provides for him to be paid an annual base salary of $400,000, subject to increase, and an annual bonus targeted at 30% of his annual base salary (later increased to 35%), subject to pro-ration in 2021. Under the offer letter, we also agreed to pay Dr. Fine a transition bonus of $50,000 within 30 days following his commencement of employment with us and $50,000 within 30 days following the first anniversary of his commencement of employment with us. The offer letter also provided for Dr. Fine to be granted the right to be issued 37,489 shares of restricted stock for a purchase price equal to fair market value on the date of issuance, which our board of directors determined equaled $1.09 per share when granted on June 24, 2022. Any unvested shares of restricted stock are subject to repurchase by us at the original purchase price in the event of a termination of employment. The restricted stock vests, and the right of repurchase thereon lapses, in two separate tranches. The first tranche, comprised of 29,054 shares, vests, and the right of repurchase thereon lapses as to 25% of the shares on the first anniversary of Dr. Fine's commencement of employment, which was September 30, 2021, and as to 1/48th of the initial number of shares monthly thereafter, subject to Dr. Fine's continued employment. The second tranche, comprised of 8,435 shares, vests, and the right of repurchase thereon lapses as to 20% of the shares on the first anniversary of Dr. Fine's commencement of employment, which was September 30, 2021, and as to 1/60th of the initial number of shares monthly thereafter, subject to Dr. Fine's continued employment and a portion of which was subject to accelerated vesting upon the attainment of certain clinical milestones. Dr. Fine's offer letter also provided for us to reimburse Dr. Fine up to $10,000 in legal fees incurred in negotiating the offer letter.

In addition, Dr. Fine's offer letter provides that in the event his employment with us is terminated at any time other than following or preceding the occurrence of a sale event (as defined in the offer letter) by us other than for cause (as defined in the offer letter), death or disability or Dr. Fine resigns for good reason, Dr. Fine is entitled to receive: 0.75 times his annual base salary and target bonus (or 1 times his annual base salary and target bonus if Dr. Fine's termination would have occurred in his first year of employment), monthly payments for continued healthcare coverage for up to 9 months, accelerated vesting of all unvested equity awards that would have vested in the 9-month period (or 12-month period if the termination would have occurred during the first year of Dr. Fine's employment) immediately following his termination of employment, a lump sum payment of any unpaid portion of his transition bonus and payment of any earned but unpaid annual bonus. In the event such a termination or resignation occurs during the period commencing 3 months prior to a sale event and ending 12 months after the sale event, Dr. Fine is entitled to receive: a lump sum payment of 12 months of his base salary, a lump sum payment of any earned and unpaid bonus for the prior year and target bonus opportunity for the year in which his termination occurs, a lump sum payment of any unpaid portion of the transition bonus, a monthly payment for continued healthcare coverage for up to 12 months, accelerated

vesting of all unvested equity awards with time-based or time and performance-based vesting (any awards subject to solely performance-based vesting shall be treated as specified in the applicable award agreement) and extended exercisability for any stock options until the earlier of 12 months following Dr. Fine's date of termination or the original expiration date applicable to such options. All severance payments and benefits are contingent on Dr. Fine timely delivering a general release of claims against us.

In August 2023, we entered into a transition and separation agreement with Dr. Fine, pursuant to which Dr. Fine ceased serving as our Chief Medical Officer as of September 1, 2023 and transitioned to the part-time position of Strategic Advisor, in which he is expected to serve through the earlier of the completion of this offering or December 31, 2023. Under the transition and separation agreement, we adjusted Dr. Fine's base salary to $7,000 per week while serving as Strategic Advisor and provided for his continued eligibility to participate in our benefit programs in accordance with their terms. The transition and separation agreement also modified 7,370 shares of Dr. Fine's restricted stock to vest in four equal monthly installments over the transition period, such vesting to be accelerated upon the completion of this offering or if we terminate Dr. Fine's employment for other than cause (as defined in his offer letter) or disparagement prior to December 31, 2023.

In exchange for the release included in the transition and separation agreement, we paid Dr. Fine $323,490, which constituted 9 months of his base salary and target bonus less $100,000, accelerated the vesting of his options and restricted stock with respect to that number of shares that, in the aggregate, were scheduled to vest through June 1, 2024, and reimbursed up to $10,000 of legal fees incurred in negotiating the transition and separation agreement. In the event Dr. Fine provides a second release at the end of his transition period, we have agreed to pay him $100,000, directly pay, or reimburse him for, continued healthcare premiums for up to 9 months and, if his employment terminates immediately prior to this offering, we terminate his employment for other than cause or disparagement or he remains employed part-time through December 31, 2023, extend the exercisability of his vested stock options through the first anniversary of his termination date.

Equity incentive compensation plans

The following summarizes the material terms of the equity incentive compensation plans in which our NEOs will be eligible to participate following the consummation of this offering and our 2021 Stock Option and Grant Plan, or 2021 Plan, under which we have previously made periodic grants of equity and equity-based awards to our NEOs and other key employees.

2023 incentive award plan

We have adopted the 2023 Incentive Award Plan (2023 Plan), which became effective on the day prior to the first public trading date of our common stock. The principal purpose of the 2023 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2023 Plan, as it is currently contemplated, are summarized below.

Share reserve. Under the 2023 Plan, a number of shares of our common stock equal to 10% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) plus any shares of our common stock reserved for future issuance under our 2021 Plan that have not been issued pursuant to any outstanding equity grants, are initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards and other stock-based awards. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2023 Plan will be increased by (i) the number of shares represented by awards outstanding under our prior plan (Prior Plan Awards), that become available for issuance under the counting provisions described below following the effective date and (ii) an annual increase on each January 1 beginning in 2024 and ending in 2033, equal to the lesser of (A) 5.0% of the

shares of our common stock outstanding (on an as converted basis) on the immediately preceding December 31 and (B) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than a number of shares equal to 75% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) may be issued upon the exercise of incentive stock options.

The following counting provisions are in effect for the share reserve under the 2023 Plan:

- to the extent that an award (including a Prior Plan Award) terminates, expires or lapses for any reason or an award is settled in cash without the delivery of shares, any shares subject to the award at such time will be available for future grants under the 2023 Plan;
- to the extent shares are tendered or withheld to satisfy the grant, exercise price or tax withholding obligation with respect to any award under the 2023 Plan or Prior Plan Award, such tendered or withheld shares will be available for future grants under the 2023 Plan;
- to the extent shares subject to stock appreciation rights are not issued in connection with the stock settlement of stock appreciation rights on exercise thereof, such shares will be available for future grants under the 2023 Plan;
- to the extent that shares of our common stock are repurchased by us prior to vesting so that shares are returned to us, such shares will be available for future grants under the 2023 Plan;
- the payment of dividend equivalents in cash in conjunction with any outstanding awards or Prior Plan Awards will not be counted against the shares available for issuance under the 2023 Plan; and
- to the extent permitted by applicable law or any exchange rule, shares issued in assumption of, or in substitution for, any outstanding awards of any entity acquired in any form of combination by us or any of our subsidiaries will not be counted against the shares available for issuance under the 2023 Plan.

In addition, the sum of the grant date fair value of all equity-based awards and the maximum that may become payable pursuant to all cash-based awards to any individual for services as a non-employee director during any calendar year may not exceed $1.5 million initially and $1.0 million annually thereafter.

Administration. The compensation committee of our board of directors is expected to administer the 2023 Plan unless our board of directors assumes authority for administration. The compensation committee must consist of at least three members of our board of directors, each of whom is intended to qualify as a “non-employee director” for purposes of Rule 16b-3 under the Exchange Act and an “independent director” within the meaning of the rules of the applicable stock exchange, or other principal securities market on which shares of our common stock are traded. The 2023 Plan provides that the board or compensation committee may delegate its authority to grant awards to employees other than executive officers and certain senior executives of the company to a committee consisting of one or more members of our board of directors or one or more of our officers, other than awards made to our non-employee directors, which must be approved by our full board of directors.

Subject to the terms and conditions of the 2023 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2023 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2023 Plan. Our board of directors may at any time remove the compensation committee as the administrator and revest in itself the authority to administer the 2023 Plan. The full board of directors will administer the 2023 Plan with respect to awards to non-employee directors.

Eligibility. Options, SARs, restricted stock and all other stock-based and cash-based awards under the 2021 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our subsidiaries. Such awards also may be granted to our directors. Only employees of our company or certain of our subsidiaries may be granted incentive stock options, or ISOs.

Awards. The 2023 Plan provides that the administrator may grant or issue stock options, SARs, restricted stock, restricted stock units, other stock- or cash-based awards and dividend equivalents, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

- *Nonstatutory stock options* (NSOs) will provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.
- *Incentive stock options* (ISOs) will be designed in a manner intended to comply with the provisions of Section 422 of the Code, and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2023 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.
- *Restricted stock* may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse, however, extraordinary dividends will generally be placed in escrow, and will not be released until restrictions are removed or expire.
- *Restricted stock units* (RSUs) may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.
- *Stock appreciation rights* (SARs) may be granted in connection with stock options or other awards, or separately. SARs granted in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over a set exercise price. The exercise price of any SAR granted under the 2023 Plan must be at least 100% of the fair market value of a share of our common stock on the date of grant. SARs under the 2023 Plan will be settled in cash or shares of our common stock, or in a combination of both, at the election of the administrator.

- *Other stock or cash-based awards* are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.
- *Dividend equivalents* represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of dividend payments dates during the period between a specified date and the date such award terminates or expires, as determined by the plan administrator. In addition, dividend equivalents with respect to shares covered by a performance award will only be paid to the participant at the same time or times and to the same extent that the vesting conditions, if any, are subsequently satisfied and the performance award vests with respect to such shares.

Any award may be granted as a performance award, meaning that the award will be subject to vesting and/or payment based on the attainment of specified performance goals.

Change in control. In the event of a change in control, unless the plan administrator elects to terminate an award in exchange for cash, rights or other property, or cause an award to accelerate in full prior to the change in control, such award will continue in effect or be assumed or substituted by the acquirer, provided that any performance-based portion of the award will be subject to the terms and conditions of the applicable award agreement. The administrator may also make appropriate adjustments to awards under the 2023 Plan and is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions.

Adjustments of awards. In the event of any stock dividend or other distribution, stock split, reverse stock split, reorganization, combination or exchange of shares, merger, consolidation, split-up, spin-off, recapitalization, repurchase or any other corporate event affecting the number of outstanding shares of our common stock or the share price of our common stock that would require adjustments to the 2023 Plan or any awards under the 2023 Plan in order to prevent the dilution or enlargement of the potential benefits intended to be made available thereunder, the administrator will make appropriate, proportionate adjustments to: (i) the aggregate number and type of shares subject to the 2023 Plan; (ii) the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any applicable performance targets or criteria with respect to such awards); and (iii) the grant or exercise price per share of any outstanding awards under the 2023 Plan.

Amendment and termination. The administrator may terminate, amend or modify the 2023 Plan at any time and from time to time. However, we must generally obtain stockholder approval to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule). Notwithstanding the foregoing, an option may be amended to reduce the per share exercise price below the per share exercise price of such option on the grant date and options may be granted in exchange for, or in connection with, the cancellation or surrender of options having a higher per share exercise price without receiving additional stockholder approval.

No incentive stock options may be granted pursuant to the 2023 Plan after the tenth anniversary of the effective date of the 2023 Plan, and no additional annual share increases to the 2023 Plan's aggregate share limit will occur from and after such anniversary. Any award that is outstanding on the termination date of the 2021 Plan will remain in force according to the terms of the 2023 Plan and the applicable award agreement.

2021 stock option and grant plan

Our board of directors adopted the 2021 Plan on July 30, 2021 and our stockholders subsequently approved the 2021 Plan on August 16, 2021 as a restatement of the 2021 Stock Incentive Plan, which itself ceased to exist upon the approval of the 2021 Plan. The 2021 Plan provides for the grant of stock options (both ISOs and NSOs), restricted stock awards, unrestricted stock awards, RSUs, or any combination of the foregoing to officers, employees, directors, consultants and other key persons of either us or any of our subsidiaries. As of November 2, 2023, options to purchase 3,402,270 shares of common stock at a weighted average exercise price per share of $6.87 and 189,664 shares of restricted stock remained outstanding under the 2021 Plan. In connection with the effectiveness of the 2023 Plan, no further awards will be granted under the 2021 Plan, but all outstanding awards will continue to be governed by their existing terms.

Administration. Our board of directors, or a committee thereof appointed by our board of directors, has the authority to administer the 2021 Plan and grant awards thereunder. The administrator has the authority to take any actions it deems necessary or advisable for the administration of the 2021 Plan, consistent with the terms of the 2021 Plan.

Awards. The 2021 Plan provides that the administrator may grant the types of awards set forth below. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

- *Stock options*. NSOs may be granted to employees and non-employees, and ISOs may be granted only to employees. The exercise price of ISOs granted to employees who at the time of grant own stock representing more than 10% of the voting power of all classes of our common stock may not be less than 110% of the fair market value per share of our common stock on the date of grant, and the exercise price of ISOs granted to any other employees, or NSOs granted to any service provider, may not be less than 100% of the fair market value per share of our common stock on the date of grant. The maximum term of each option is ten years from the grant date, or for ISOs granted to employees who at the time of grant own stock representing more than 10% of the voting power of all classes of our common stock, five years from the grant date.
- *Restricted stock*. Restricted stock may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for no consideration or repurchased by us on the terms set out in the plan, if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights, to the extent such shares are entitled to voting rights, and will have the right to receive dividends and any other distributions, if any, prior to the time when the restrictions lapse.
- *Unrestricted stock awards*. Unrestricted stock awards may be awarded to any eligible individual or sold at par value or such other purchase price as determined by the administrator. Unrestricted Stock Awards may be granted in respect of past services or other valid consideration or in lieu of cash compensation due to such individual.
- *RSUs*. RSUs may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, RSUs may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying RSUs will not be issued until the RSUs have vested, and recipients of RSUs generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.

Adjustments of awards. In the event of any significant change that occurs with respect to our common stock (through reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split or other similar transactions), the administrator will make appropriate and proportionate adjustments to: the maximum number of shares reserved for issuance under the plan, the number and kind of shares or other securities subject to any then outstanding awards under the plan, the repurchase price, if any, per share subject to each outstanding award, and the exercise price for each share subject to any then outstanding stock options under the plan, without changing the aggregate exercise price (as to which such stock options remain exercisable).

Sale event. In the event of a sale event (as defined in the 2021 Plan), the 2021 Plan and all outstanding options shall terminate unless assumed or continued by the successor or new stock options or awards of the successor are substituted equitably and proportionately as to the number and kind of shares and, if appropriate, the per share exercise prices, as such parties shall agree (after taking into account any acceleration hereunder and/or pursuant to the terms of any award agreement). Additionally, upon a sale event and in the event of the termination of the 2021 Plan, each holder will be permitted, within a set period of time prior to the consummation of the sale event and as specified by the administrator, to exercise all such options which are then exercisable or will become exercisable as of and contingent on the sale event occurring. Notwithstanding the foregoing, the administrator may make or provide for a cash payment to the holders, (without their consent) in exchange for the cancellation of the options, in accordance with the terms of the plan. For purposes of the 2021 Plan, a sale event includes the consummation of (i) the dissolution or liquidation of our company, (ii) the sale of all or substantially all of our assets to an unrelated person or entity, (iii) a merger, reorganization or consolidation pursuant to which the holders of our outstanding voting power immediately prior to such transaction do not own a majority of the outstanding voting power of the surviving or resulting entity (or its ultimate parent, if applicable), (iv) the acquisition of all or a majority of our outstanding voting stock in a single transaction or a series of related transactions by a person or group of persons, or (v) any other acquisition of our business, as determined by our board of directors; provided, however, that this offering, any subsequent public offering or another capital raising event, or a merger effected solely to change our domicile does not constitute a sale event.

Right of first refusal. In the event that a holder decides to sell or transfer their shares (other than shares of restricted stock), the holder must first give written notice to us in accordance with the plan, including the terms of the proposed sale. At any time within 30 days of receipt of such notice, the company or our assigns may elect to purchase the shares at the price and on the terms specified in the notice.

Right of repurchase. Upon a termination of service, we or our assigns have the option to repurchase shares acquired upon exercise of a stock option and shares pursuant to a restricted stock award, in each case, that are subject to a risk of forfeiture as of the termination. The repurchase price shall be the lower of the original per share purchase price paid by the holder, subject to adjustment or the current fair market value of such shares as of the date we elect to exercise our repurchase rights.

Plan amendment or termination. The administrator has the authority, at any time, to amend or discontinue our 2021 Plan, and at any time, amend or cancel any outstanding award for the purpose of compliance with applicable law or other lawful purpose but no such action shall adversely affect rights under any outstanding award without the consent of the holder of the award. The administrator may exercise its discretion to reduce the exercise price of outstanding stock options or effect repricing through cancellation of outstanding stock options and by granting such holders new awards in replacement of the cancelled stock options. In connection with the effectiveness of our 2023 Plan, no further awards will be granted under the 2021 Plan.

2023 employee stock purchase plan

We have adopted the 2023 Employee Stock Purchase Plan, which we refer to as our ESPP, which became effective on the day prior to the first public trading date of our common stock. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at periodic intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code. The material terms of the ESPP, as it is currently contemplated, are summarized below.

Administration. Subject to the terms and conditions of the ESPP, our compensation committee will administer the ESPP. Our compensation committee can delegate administrative tasks under the ESPP to the services of an agent and/or employees to assist in the administration of the ESPP. The administrator will have the discretionary authority to administer and interpret the ESPP. Interpretations and constructions of the administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. We will bear all expenses and liabilities incurred by the ESPP administrator.

Share Reserve. The maximum number of shares of our common stock which will be authorized for sale under the ESPP is equal to the sum of (i) a number of shares of common stock equal to 1.0% of our outstanding common stock after this offering and (ii) an annual increase on the first day of each year beginning in 2024 and ending in 2033, equal to the lesser of (A) 1.0% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (B) such number of shares of common stock as determined by our board of directors; provided, however, no more than an amount of shares equal to 13.75% of our outstanding common stock after this offering (without giving effect to the underwriters option to purchase additional shares in this offering) may be issued under the ESPP. The shares reserved for issuance under the ESPP may be authorized but unissued shares or reacquired shares.

Eligibility. Employees eligible to participate in the ESPP for a given offering period generally include employees who are employed by us or one of our subsidiaries on the first day of the offering period, or the enrollment date. Our employees (and, if applicable, any employees of our subsidiaries) who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (or is deemed to own through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

Participation. Employees will enroll under the ESPP by completing a payroll deduction form permitting the deduction from their compensation of at least 1.0% of their compensation but not more than 15.0% of their compensation. Such payroll deductions may be expressed as either a whole number percentage or a fixed dollar amount, and the accumulated deductions will be applied to the purchase of shares on each purchase date. However, a participant may not purchase more than 100,000 shares in each offering period and may not accrue the right to purchase shares of common stock at a rate that exceeds $25,000 in fair market value of shares of our common stock (determined at the time the option is granted) for each calendar year the option is outstanding (as determined in accordance with Section 423 of the Code). The ESPP administrator has the authority to change these limitations for any subsequent offering period.

Offering. Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods, the duration and timing of which will be determined by the ESPP administrator. However, in no event may an offering period be longer than 27 months in length.

The option purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period.

Unless a participant has previously canceled his or her participation in the ESPP before the purchase date, the participant will be deemed to have exercised his or her option in full as of each purchase date. Upon exercise, the participant will purchase the number of whole shares that his or her accumulated payroll deductions will buy at the option purchase price, subject to the participation limitations listed above.

A participant may cancel his or her payroll deduction authorization at any time prior to the end of the offering period. Upon cancellation, the participant will have the option to either (i) receive a refund of the participant's account balance in cash without interest or (ii) exercise the participant's option for the current offering period for the maximum number of shares of common stock on the applicable purchase date, with the remaining account balance refunded in cash without interest. Following at least one payroll deduction, a participant may also decrease (but not increase) his or her payroll deduction authorization once during any offering period. If a participant wants to increase or decrease the rate of payroll withholding, he or she may do so effective for the next offering period by submitting a new form before the offering period for which such change is to be effective.

A participant may not assign, transfer, pledge or otherwise dispose of (other than by will or the laws of descent and distribution) payroll deductions credited to a participant's account or any rights to exercise an option or to receive shares of our common stock under the ESPP, and during a participant's lifetime, options in the ESPP shall be exercisable only by such participant. Any such attempt at assignment, transfer, pledge or other disposition will not be given effect.

Adjustments upon changes in recapitalization, dissolution, liquidation, merger or asset sale. In the event of any increase or decrease in the number of issued shares of our common stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock, or any other increase or decrease in the number of shares of common stock effected without receipt of consideration by us, we will proportionately adjust the aggregate number of shares of our common stock offered under the ESPP, the number and price of shares which any participant has elected to purchase under the ESPP and the maximum number of shares which a participant may elect to purchase in any single offering period. If there is a proposal to dissolve or liquidate us, then the ESPP will terminate immediately prior to the consummation of such proposed dissolution or liquidation, and any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our dissolution or liquidation. We will notify each participant of such change in writing at least 10 business days prior to the new exercise date. If we undergo a merger with or into another corporation or sell all or substantially all of our assets, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or the parent or subsidiary of the successor corporation. If the successor corporation refuses to assume the outstanding options or substitute equivalent options, then any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our proposed sale or merger. We will notify each participant of such change in writing at least ten business days prior to the new exercise date.

Amendment and termination. Our board of directors may amend, suspend or terminate the ESPP at any time. However, the board of directors may not amend the ESPP without obtaining stockholder approval within 12 months before or after such amendment to the extent required by applicable laws.

Certain relationships and related-party transactions

The following includes a summary of transactions since January 1, 2020 and any currently proposed transactions, to which we were or are to be a participant, in which (i) the amount involved exceeded or will exceed the lesser of $120,000 and 1% of our total assets; and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any affiliate or member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the sections titled “Director compensation” and “Executive compensation.”

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that we would pay or receive, as applicable, in arm’s-length transactions.

Related-party agreements in effect prior to this offering

Common stock issuance

In October 2020 and November 2020, we entered into stock subscription agreements pursuant to which we issued 375,870 and 73,700 shares of our common stock at a price of $0.0136 per share to Crystal Mackall, M.D. and Samsara BioCapital, L.P. (Samsara), respectively, for an aggregate of 449,570 shares of common stock issued. In April 2022, we waived our right to repurchase 112,761 shares of common stock at a price of $0.0136 per share from Dr. Mackall. Dr. Mackall is a Co-Founder of CARGO and a member of our board of directors and Samsara is a holder of more than 5% of our capital stock. For further details, see the information provided in footnotes 9 and 1 to the table in the section titled “Principal stockholders.”

The table below sets forth the number of shares of our common stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members.

Name[1]	Common stock (#)		Aggregate purchase price ($)
Samsara BioCapital, L.P.[2]	73,700	$	1,000
Crystal Mackall, M.D.[3]	375,870	$	5,100

(1) For additional information regarding these stockholders and their equity holdings, see the section titled “Principal stockholders.”

(2) Samsara BioCapital, L.P. beneficially owns more than 5% of our outstanding capital. Mr. Bassan, a member of our board of directors, was designated to our board of directors by Samsara. Mr. Bassan is a Vice President at Samsara.

(3) Crystal Mackall, M.D. is a Co-Founder of CARGO and member of our board of directors.

Convertible note and convertible preferred stock financings

Convertible note purchase agreement

Between April 2022 and January 2023, we issued approximately $32.0 million in convertible promissory notes (the Convertible Notes), approximately $18.2 million and $10.9 million of which notes were issued to Samsara and Red Tree Venture Fund, L.P. (Red Tree), respectively. In February 2023, the Convertible Notes were settled with shares of our Series A-2 convertible preferred stock (the Series A-2 Preferred Stock) and we issued 3,229,851 shares of Series A-2 Preferred Stock to the holders of the Convertible Notes. Each of Samsara and Red Tree are holders of more than 5% of our capital stock. For further details, see the information provided in footnotes 1 and 2 to the table in the section titled “Principal stockholders.”

Series Seed convertible preferred stock financing

In February 2021, we entered into a Series Seed convertible preferred stock purchase agreement (the Series Seed Purchase Agreement), with various investors (the Series Seed Investors), pursuant to which we issued an aggregate of 405,350 shares of our Series Seed convertible preferred stock (the Series Seed Preferred Stock) at $13.57 per share for aggregate proceeds of $5.5 million in the initial closing.

In accordance with the terms of the Series Seed Purchase Agreement, each of the Series Seed Investors agreed to purchase additional shares of Series Seed Preferred Stock if certain Company milestone events (as set forth in the Series Seed Purchase Agreement) occurred. In January 2022, the Company milestone events occurred, and the Series Seed Investors purchased an additional 405,350 shares of Series Seed Preferred Stock at $13.57 per share for aggregate proceeds of $5.5 million in the milestone closing.

Series A-1 convertible preferred stock financing

In February 2023, we entered into a Series A-1 convertible preferred stock purchase agreement (the Series A-1 Purchase Agreement), with various investors (the Series A Investors), pursuant to which we issued an aggregate of 5,072,919 shares of our Series A-1 convertible preferred stock (the Series A-1 Preferred Stock) at $13.57 per share for aggregate proceeds of $68.8 million in two closings. The first closing occurred in February 2023, at which time we issued 4,491,745 shares of our Series A-1 Preferred Stock for gross proceeds of approximately $60.9 million. The second closing also occurred in February 2023, at which time we issued an additional 581,174 shares of our Series A-1 Preferred Stock for gross proceeds of approximately $7.9 million.

The Series A-1 Purchase Agreement also committed the Series A Investors to purchasing up to 9,723,089 additional shares of Series A-1 Preferred Stock at a fixed price of $13.57 per share in one or more subsequent closings upon (i) the occurrence of certain clinical milestones certified by the Company's board of directors and approved by holders of a majority of the then outstanding shares of Series A-1 Preferred Stock (the Requisite Holder Approval) or (ii)(A) the unanimous approval of the Company's board of directors to waive certain milestones and (B) Requisite Holder Approval.

In July 2023, upon the occurrence of certain clinical milestones, we issued an aggregate of 3,381,941 shares of our Series A-1 Preferred Stock at $13.57 per share to the Series A Investors for aggregate proceeds of $45.9 million in a second closing.

In October 2023, upon the unanimous approval of the Company's board of directors to waive certain milestones and Requisite Holder Approval, we issued an aggregate of 6,341,148 shares of our Series A-1 Preferred Stock at $13.57 per share to the Series A Investors for aggregate proceeds of $86.0 million in a third closing.

The table below sets forth the number of shares of Series Seed Preferred Stock, Series A-1 Preferred Stock and Series A-2 Preferred Stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of Series Seed Preferred Stock, Series A-1 Preferred Stock and Series A-2 Preferred Stock in the table below will convert into one share of our common stock immediately prior to the completion of this offering.

Name[1]	Series Seed convertible preferred stock (#)	Series A-1 convertible preferred stock (#)	Series A-2 convertible preferred stock (#)	Aggregate purchase price ($)
Samsara BioCapital, L.P.[2]	663,300	884,400	1,833,623	$ 39,187,097
Red Tree Venture Fund, L.P.[3]	73,700	626,449	1,105,158	$ 20,429,032
Perceptive Xontogeny Venture Fund II, LP[4]	—	2,579,502	—	$ 35,000,000
Entities affiliated with Third Rock Ventures[5]	—	2,211,002	—	$ 30,000,000
Nextech VII Oncology SCSP[6]	—	1,842,502	—	$ 25,000,000
Janus Henderson Biotech Innovation Master Fund Limited[7]	—	1,474,001	—	$ 20,000,000
Entities affiliated with RTW Funds[8]	—	1,842,499	—	$ 25,000,000

(1) For additional information regarding these stockholders and their equity holdings, see the section titled “Principal stockholders.”

(2) Samsara beneficially owns more than 5% of our outstanding capital. Mr. Bassan, a member of our board of directors, was designated to our board by Samsara. Mr. Bassan is a Vice President at Samsara.

(3) Red Tree beneficially owns more than 5% of our outstanding capital. Dr. Lukatch, a member of our board of directors at the time of the Series A-1 convertible preferred stock financing, was designated to our board by Red Tree. Dr. Lukatch is Founder and Managing Partner of Red Tree.

(4) Perceptive Xontogeny Venture Fund II, LP (Xontogeny) beneficially owns more than 5% of our outstanding capital. Dr. Luca, a member of our board of directors who resigned from the board in October 2023, was designated to our board by Xontogeny. Dr. Luca is a Principal at Xontogeny.

(5) Third Rock Ventures V, L.P. and Third Rock Ventures VI, L.P. (collectively, Third Rock Ventures) beneficially owns more than 5% of our outstanding capital. Dr. Huber, a member of our board of directors, was designated to our board by Third Rock Ventures. Dr. Huber is a Partner at Third Rock Ventures.

(6) Nextech VII Oncology SCSP beneficially owns more than 5% of our outstanding capital.

(7) Janus Henderson Biotech Innovation Master Fund Limited beneficially owns more than 5% of our outstanding capital.

(8) RTW Biotech Opportunities Ltd., RTW Innovation Master Fund, Ltd., RTW Master Fund, Ltd. and RTW Venture Fund Limited (collectively, RTW Funds) beneficially own more than 5% of our outstanding capital.

Investors’ rights agreement

We are party to an investors’ rights agreement with the purchasers of our outstanding convertible preferred stock, including entities with which certain of our directors are affiliated. Following the consummation of this offering, the holders of approximately 18,910,251 shares of our common stock, including the shares of common stock issuable upon the conversion of our convertible preferred stock, are entitled to rights with respect to the registration of their shares under the Securities Act. For a more detailed description of these registration rights, see the section titled “Description of capital stock—Registration rights.” The investors’ rights agreement also provides for a right of first

offer in favor of certain holders of convertible preferred stock with regard to certain issuances of our capital stock. The rights of first offer will not apply to, and will terminate upon the consummation of, this offering.

Voting agreement

We are party to a voting agreement with certain holders of our common stock and convertible preferred stock. Upon the conversion of all outstanding shares of convertible preferred stock into common stock in connection with the consummation of this offering, the voting agreement will terminate. For a description of the voting agreement, see the section titled “Management—Board structure and composition—Voting arrangements.

Right of first refusal and co-sale agreement

We are party an amended and restated right of first refusal and co-sale agreement with certain holders of our common stock and convertible preferred stock. This agreement provides for rights of first refusal and co-sale relating to the shares of our common stock held by the parties to the agreement. Upon the consummation of this offering, the amended and restated right of first refusal and co-sale agreement will terminate.

Other transactions

We have entered into offer letter agreements with our executive officers that, among other things, provide for certain compensatory and change in control benefits, as well as severance benefits. For a description of these agreements with our named executive officers, see the section titled “Executive compensation—Executive compensation arrangements.”

We have also granted stock options and restricted stock to our executive officers and certain of our directors. For a description of these equity awards, see the sections titled “Executive compensation” and “Director compensation.”

Director and officer indemnification

We have entered into indemnification agreements with certain of our current executive officers and directors, and intend to enter into new indemnification agreements with each of our current executive officers and directors before the completion of this offering.

Our amended and restated certificate of incorporation also provides that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our officer or director, or served any other enterprise at our request as an officer or director. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

Related-party transaction policy

We have a written related-party transaction policy, to be effective upon the completion of this offering, that applies to our executive officers, directors, director nominees, holders of more than five percent of any class of our voting securities and any member of the immediate family of, and any entity affiliated with, any of the foregoing persons. Such persons will not be permitted to enter into a related-party transaction with us without the prior consent of our audit committee, or other independent members of our board of directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. Any request for us to enter into a transaction with an executive officer, director, director nominee, principal stockholder, or any of their immediate family members or affiliates, in which the amount involved exceeds $120,000 must first be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee will consider the relevant facts and circumstances available and deemed relevant to our audit committee, including, but not limited to, the commercial reasonableness of the terms of the transaction and the materiality and character of the related-party’s direct or indirect interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Principal stockholders

The following table sets forth information regarding beneficial ownership of our common stock as of November 2, 2023 by:

- each person whom we know to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all directors and executive officers as a group.

In accordance with the rules of the SEC, beneficial ownership includes voting or investment power with respect to securities and includes the shares issuable pursuant to stock options that are exercisable within 60 days of November 2, 2023. Shares issuable pursuant to stock options are deemed outstanding for computing the percentage of the person holding such options but are not outstanding for computing the percentage of any other person.

We have based our calculation of the percentage of beneficial ownership prior to this offering on 19,942,959 shares of our common stock outstanding and held of record by approximately 170 stockholders as of November 2, 2023, which gives effect to the automatic conversion of all outstanding shares of convertible preferred stock into shares of our common stock immediately prior to the completion of this offering. We have based our calculation of the percentage of beneficial ownership after this offering on 38,692,959 shares of our common stock outstanding as of November 2, 2023, which gives effect to the adjustments described in the prior sentence and further reflects the issuance of 18,750,000 shares of common stock in this offering, assuming that the underwriters will not exercise their option to purchase up to an additional 2,812,500 shares of our common stock.

Unless otherwise indicated, the address for each listed stockholder is: c/o CARGO Therapeutics, Inc., 1900 Alameda De Las Pulgas, Suite 350, San Mateo, California 94403. To our knowledge, except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

Name of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
Greater than 5% owners:			
Samsara BioCapital, L.P.(1)	3,455,023	17.3%	8.9%
Red Tree Venture Fund, L.P.(2)	1,805,307	9.1%	4.7%
Perceptive Xontogeny Venture Fund II, LP(3)	2,579,502	12.9%	6.7%
Funds affiliated with Third Rock Ventures(4)	2,211,002	11.1%	5.7%
Nextech VII Oncology SCSP(5)	1,842,502	9.2%	4.8%
Janus Henderson Biotech Innovation Master Fund Limited(6)	1,474,001	7.4%	3.8%
Funds affiliated with RTW Funds(7)	1,842,499	9.2%	4.8%
Named executive officers and directors:			
Abraham Bassan	—	*	*
Gina Chapman(8)	103,905	*	*
Shishir Gadam, Ph.D.(9)	29,480	*	*
Reid Huber, Ph.D.	—	*	*
David Lubner(10)	2,878	*	*
Crystal Mackall, M.D.(11)	378,424	1.9%	*
John Orwin(12)	31,261	*	*
Anup Radhakrishnan(13)	7,711	*	*
Krishnan Viswanadhan, Pharm.D(14)	3,173	*	*
Ginna Laport, M.D.	—		
All executive officers and directors as a group (10 persons)(15)	556,832	2.8%	1.4%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 73,700 shares of our common stock, (ii) 663,300 shares of our common stock issuable upon conversion of our Series Seed convertible preferred stock directly held by Samsara BioCapital, L.P. (Samsara LP), (iii) 884,400 shares of our common stock issuable upon conversion of our Series A-1 convertible preferred stock directly held by Samsara LP and (iv) 1,833,623 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock directly held by Samsara LP. Samsara BioCapital GP, LLC (Samsara LLC) is the general partner of Samsara LP and may be deemed to beneficially own the shares held by Samsara LP. Dr. Srinivas Akkaraju, MD, Ph.D. has voting and investment power over the shares held by Samsara GP and, accordingly, may be deemed to beneficially own the shares held by Samsara LP. Samsara LLC disclaims beneficial ownership in these shares except to the extent of its respective pecuniary interest therein. The principal address for Samsara BioCapital, L.P. is 628 Middlefield Road, Palo Alto, California 94301.

(2) Consists of (i) 73,700 shares of our common stock issuable upon conversion of our Series Seed convertible preferred stock directly held by Red Tree Venture Fund, L.P. (Red Tree), (ii) 626,449 shares of our common stock issuable upon conversion of our Series A-1 convertible preferred stock directly held by Red Tree and (iii) 1,105,158 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock directly held by Red Tree. Red Tree GP, L.P. (Red Tree GP I) is the general partner of Red Tree and may be deemed to have sole voting and dispositive power over the shares held by Red Tree. Red Tree GP I and Heath Lukatch, the Managing Director of Red Tree GP I who may be deemed to share voting and dispositive power over the reported securities, disclaim beneficial ownership of the reported securities held by Red Tree except to the extent of any pecuniary interest therein. The principal address for Red Tree Venture Fund, L.P. is 2055 Woodside Road, Suite 270, Redwood City, California 94061.

(3) Consists of 2,579,502 shares of our common stock issuable upon conversion of our Series A-1 convertible preferred stock directly held by Perceptive Xontogeny Venture Fund II, LP (Xontogeny). Perceptive Venture Advisors, LLC (the Venture Advisor) serves as the investment advisor to Xontogeny and is an affiliate of Perceptive Advisors LLC (the Advisor). Joseph Edelman is the managing member of the Advisor. The Venture Advisor, the Advisor and Mr. Edelman disclaim, for purposes of Section 16 of the Securities Exchange Act of 1934, beneficial ownership of such securities, except to the extent of his or its indirect pecuniary interest therein, and this report shall not be deemed an admission that they are the beneficial owner of such securities for purposes of Section 16 or for any other purposes. The principal address for Perceptive Xontogeny Venture Fund II, LP is 51 Astor Place, 10th Floor, New York, New York 10003.

(4) Consists of (i) 1,737,216 shares of our common stock held by Third Rock Ventures V, L.P. and (ii) 473,786 shares of our common stock held by Third Rock Ventures VI, L.P. (together with Third Rock Ventures V, L.P., Third Rock Ventures). The general partner of Third Rock Ventures is Third Rock Ventures GP V, L.P. (TRV GP V). The general partner of TRV GP V is TRV GP V, LLC (TRV GP V LLC). Abbie Celniker, Ph.D.; Robert Tepper, M.D.; Reid Huber, Ph.D.; Jeffrey Tong, Ph.D.; Kevin Gillis; Neil Exter; and Cary Pfeffer, M.D. are the

managing members of TRV GP V, LLC who collectively make voting and investment decisions with respect to shares held by Third Rock Ventures V, L.P. The principal address for Third Rock Ventures V, L.P. is 201 Brookline Avenue, Suite 1401, Boston, Massachusetts 02215.

(5) Consists of 1,842,502 shares of our common stock issuable upon conversion of our Series A-1 convertible preferred stock directly held by Nextech VII Oncology SCSP. Nextech VII GP S.à.r.l. is the general partner of Nextech VII Oncology SCSP and may be deemed to beneficially own the shares held by Nextech VII Oncology SCSP. Costas Constantinides, Ian Charoub and Rocco Sgobbo, as managers of Nextech VII GP S.à.r.l., have voting and investment power over the shares held by Nextech VII Oncology SCSP and, accordingly, may be deemed to beneficially own the shares held by Nextech VII Oncology SCSP. The principal address for Nextech VII Oncology SCSP is 8 rue Lou Hemmer, L 1748 Senningerberg, Luxembourg.

(6) Consists of 1,474,001 shares of our common stock issuable upon conversion of our Series A-1 convertible preferred stock directly held by Janus Henderson Biotech Innovation Master Fund Limited. Janus Henderson Investors US LLC is an investment adviser to Janus Henderson Biotech Innovation Master Fund Limited, and, in such capacity, exercises shared voting and dispositive power over the shares held by Janus Henderson Biotech Innovation Master Fund Limited and may be deemed to beneficially own such shares. Andrew Acker, Daniel S. Lyons and Agustin Mohedas serve as portfolio managers of Janus Henderson Biotech Innovation Master Fund Limited and as such may share voting and dispositive power over the shares held by Janus Henderson Biotech Innovation Master Fund Limited. The principal address for Janus Henderson Biotech Innovation Master Fund Limited is c/o Janus Henderson Investors US LLC, 151 Detroit Street, Denver, Colorado 80206.

(7) Consists of 1,842,499 shares of our common stock issuable upon conversion of our Series A-1 convertible preferred stock held in the aggregate by RTW Master Fund, Ltd., RTW innovation Master Fund, Ltd. and RTW Biotech Opportunities Fund Ltd. (collectively, the RTW Funds). RTW Investments, LP (RTW), in its capacity as the investment manager of the RTW Funds, has the power to vote and the power to direct the disposition of the shares held by the RTW Funds. Accordingly, RTW may be deemed to be the beneficial owner of such securities. Roderick Wong, M.D., as the Managing Partner of RTW, has the power to direct the vote and disposition of the securities held by RTW. Dr. Wong disclaims beneficial ownership of the shares held by the RTW Funds, except to the extent of his pecuniary interest therein. The address and principal office of RTW Investments, LP is 40 10th Avenue, Floor 7, New York, NY 10014, and the address of Dr. Wong and each of the RTW Funds is c/o RTW Investments, LP, 40 10th Avenue, Floor 7, New York, NY 10014.

(8) Consists of 103,905 shares of our common stock issued pursuant to the grant of restricted stock awards.

(9) Consists of 29,480 shares of our common stock issued pursuant to the grant of restricted stock awards.

(10) Consists of 2,878 shares of our common stock that may be acquired pursuant to the exercise of stock options issuable upon conversion within 60 days of November 2, 2023.

(11) Consists of 378,424 shares of our common stock held directly by Dr. Mackall.

(12) Consists of 31,261 shares of our common stock that may be acquired pursuant to the exercise of stock options issuable upon conversion within 60 days of November 2, 2023.

(13) Consists of (i) 6,446 shares of our common stock outstanding and (ii) 1,265 shares of our common stock that may be acquired pursuant to the exercise of stock options issuable upon conversion within 60 days of November 2, 2023.

(14) Consists of 3,173 shares of our common stock that may be acquired pursuant to the exercise of stock options issuable upon conversion within 60 days of November 2, 2023.

(15) Consists of (i) 518,255 shares beneficially owned by our current directors and executive officers and (ii) 38,577 shares subject to options exercisable within 60 days of November 2, 2023.

Description of capital stock

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the completion of this offering, the amended and restated investors' rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prosSpectus is part.

General

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 500,000,000 shares of common stock, par value $0.001 per share, and 50,000,000 shares of preferred stock, par value $0.001 per share.

Common stock

Outstanding shares

As of June 30, 2023, we had 10,199,455 shares of common stock outstanding, held of record by 44 stockholders, assuming the conversion of all of our outstanding shares of convertible preferred stock into 9,113,470 shares of common stock immediately prior to the completion of this offering.

Voting rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66-2/3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, including the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights, preferences and privileges

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully paid and nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred stock

Upon the completion of this offering, all of our currently outstanding shares of convertible preferred stock will convert into common stock, and we will not have any shares of preferred stock outstanding. Immediately prior to the completion of this offering, our amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. From and after the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 50,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Stock options

As of June 30, 2023, we had outstanding options to purchase an aggregate of 2,147,565 shares of our common stock, with a weighted-average exercise price of $4.73 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive compensation—Equity compensation plans.”

Registration rights

Upon the completion of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors’ rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will terminate upon the earliest of (i) the closing of a "Deemed Liquidation Event," as such term is defined in our amended and restated certificate of incorporation (as currently in effect), (ii) with respect to each stockholder, such date, on or after the completion of this offering, on which all registrable shares held by such stockholder may immediately be sold during any three-month period pursuant to Rule 144 of the Securities Act or another similar exemption and (iii) the third anniversary of the completion of this offering.

Demand registration rights

Upon the completion of this offering, holders of approximately 18,910,251 shares of our common stock issuable upon conversion of outstanding convertible preferred stock will be entitled to certain demand registration rights. Beginning 180 days following the effectiveness of the registration statement of which this prospectus is a part, certain major investors holding, collectively, holding at least 40% of registrable securities may request that we register all or a portion of their shares, subject to certain specified exceptions. If any of these holders exercises its demand registration rights, then holders of approximately 18,910,251 shares of our common stock issuable upon the shares of our convertible preferred stock in connection with this offering will be entitled to register their shares, subject to specified conditions and limitations in the corresponding offering.

Piggyback registration rights

In connection with this offering, holders of approximately 18,910,251 shares of our common stock issuable upon conversion of outstanding convertible preferred stock are entitled to their rights to notice of this offering and to include their shares of registrable securities in this offering. The requisite percentage of these stockholders are expected to waive all such stockholders' rights to notice of this offering and to include their shares of registrable securities in this offering. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

S-3 registration rights

Upon the completion of this offering, the holders of approximately 18,910,251 shares of our common stock issuable upon conversion of outstanding convertible preferred stock will initially be entitled to certain Form S-3 registration rights. Certain major investors holding at least 20% of registrable securities may request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds $5.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Election and removal of directors; vacancies

The exact number of directors will be fixed from time to time by resolution of the board. Directors will be elected by a plurality of the votes of the shares of our capital stock present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

No director may be removed except for cause, and directors may be removed for cause only by an affirmative vote of shares representing not less than a majority of the shares then entitled to vote at an election of directors.

Any vacancy occurring on the board of directors and any newly created directorship may be filled only by a majority of the remaining directors in office.

Staggered board

Upon the completion of this offering, our board of directors will be divided into three classes serving staggered three-year terms. Class I, Class II and Class III directors will serve until our annual meetings of stockholders in 2024, 2025 and 2026, respectively. At each annual meeting of stockholders, directors will be elected to succeed the class of directors whose terms have expired. This classification of our board of directors could have the effect of increasing the length of time necessary to change the composition of a majority of the board of directors. In general, at least two annual meetings of stockholders will typically be necessary for stockholders to effect a change in a majority of the members of the board of directors.

Limitation on action by written consent

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that holders of our common stock will not be able to act by written consent without a meeting.

Stockholder meetings

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that special meetings of our stockholders may be called only by the chairperson of the board, our chief executive officer (or president, in the absence of a chief executive officer) or a majority of the directors. Our amended and restated certificate of incorporation and our amended and restated bylaws specifically deny any power of any other person to call a special meeting.

Amendment of certificate of incorporation

The provisions of our amended and restated certificate of incorporation described under the subsections titled “—Election and removal of directors; vacancies,” “—Stockholder meetings,” “—Limitation on action by written consent,” “—Limitation of liability of directors and officers,” “—Common stock—Voting rights” and “—Forum selection” and provisions relating to amendments to our amended and restated certificate of incorporation may be amended only by the affirmative vote of holders of at least 66-2/3% of the voting power of our outstanding shares of voting stock. The affirmative vote of holders of at least a majority of the voting power of our outstanding shares of stock will generally be required to amend other provisions of our amended and restated certificate of incorporation.

Amendment of bylaws

Certain provisions of our amended and restated bylaws may generally be altered, amended or repealed, and new bylaws may be adopted, with the affirmative vote of a majority of directors present at any regular or special meeting of the board of directors called for that purpose, provided that any alteration, amendment, or repeal of, or adoption of any bylaw inconsistent with specified provisions of the bylaws, including those related to special and annual meetings of stockholders, action of stockholders by written consent, nomination of directors, transfers of capital stock and dividends requires the affirmative vote of at least 66-2/3% of all directors in office at a meeting called for that purpose.

All other provisions of our amended and restated bylaws may generally be altered, amended or repealed, and new bylaws may be adopted, with the affirmative vote of holders of 66-2/3 % of the voting power of our outstanding shares of voting stock.

Other limitations on stockholder actions

Our amended and restated bylaws impose some procedural requirements on stockholders who wish to:

- make nominations in the election of directors;
- propose that a director be removed;
- propose any repeal or change in our amended and restated bylaws; or
- propose any other business to be brought before an annual or special meeting of stockholders.

Under these procedural requirements, in order to bring a proposal before a meeting of stockholders, a stockholder must deliver timely notice of a proposal pertaining to a proper subject for presentation at the meeting to our corporate secretary along with the following:

- a description of the business or nomination to be brought before the meeting and the reasons for conducting such business at the meeting;
- the stockholder's name and address;
- any material interest of the stockholder in the proposal;
- the number of shares beneficially owned by the stockholder and evidence of such ownership; and
- the names and addresses of all persons with whom the stockholder is acting in concert and a description of all arrangements and understandings with those persons, and the number of shares such persons beneficially own.

To be timely, a stockholder must generally deliver notice:

- in connection with an annual meeting of stockholders, not less than 120 nor more than 150 days prior to the date on which the annual meeting of stockholders was held in the immediately preceding year, but in the event that the date of the annual meeting is more than 30 days before or more than 70 days after the anniversary date of the preceding annual meeting of stockholders, a stockholder notice will be timely if received by us not later than the close of business on the later of (i) not less than 70 nor more than 120 days prior to the date of the annual meeting and (ii) the 10th day following the day on which we first publicly announce the date of the annual meeting; or
- in connection with the election of a director at a special meeting of stockholders, during the period not less than 120 nor more than 150 days prior to the date of the special meeting, or the 10th day following the day on which a notice of the date of the special meeting was mailed to the stockholders or the public disclosure of that date was made.

In order to submit a nomination for our board of directors, a stockholder must also submit all information with respect to the nominee that would be required to be included in a proxy statement, as well as other information. If a stockholder fails to follow the required procedures, the stockholder's proposal or nominee will be ineligible and will not be voted on by our stockholders.

Limitation of liability of directors and officers

Our amended and restated certificate of incorporation provides that no director will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except as required by applicable law, as in effect from time to time. Section 102(b)(7) of the Delaware General Corporation Law

permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to our company or our stockholders;
- any act or omission not in good faith or which involved intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; and
- any transaction from which the director derived an improper personal benefit.

As a result, neither we nor our stockholders have the right, through stockholders' derivative suits on our behalf, to recover monetary damages against a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior, except in the situations described above.

Our amended and restated certificate of incorporation also provides that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our director or officer, or served any other enterprise at our request as a director or officer. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

Forum selection

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer, or other employee of our company to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation and bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. 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 the foregoing forum selection provisions. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The enforceability of similar federal court choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find this type of provision to be inapplicable or unenforceable. If a court were to find either of the choice of forum provisions

contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

The choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the company or our directors, officers or other employees, which may discourage such lawsuits against the company and our directors, officers and other employees and result in increased costs for investors to bring a claim.

Delaware Business Combination Statute

We have elected to be subject to Section 203 of the Delaware General Corporation Law. Section 203 prevents an "interested stockholder," which is defined generally as a person owning 15% or more of a corporation's voting stock, or any affiliate or associate of that person, from engaging in a broad range of "business combinations" with the corporation for three years after becoming an interested stockholder unless:

- the board of directors of the corporation had previously approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, that person owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, other than statutorily excluded shares; or
- following the transaction in which that person became an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Under Section 203, the restrictions described above also do not apply to specific business combinations proposed by an interested stockholder following the announcement or notification of designated extraordinary transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation's directors, if such extraordinary transaction is approved or not opposed by a majority of the directors who were directors prior to any person becoming an interested stockholder during the previous three years or were recommended for election or elected to succeed such directors by a majority of such directors.

Section 203 may make it more difficult for a person who would be an interested stockholder to effect various business combinations with a corporation for a three-year period. Section 203 also may have the effect of preventing changes in our management and could make it more difficult to accomplish transactions that our stockholders may otherwise deem to be in their best interests.

Anti-takeover effects of some provisions

Certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws could make the following more difficult:

- acquisition of control of us by means of a proxy contest, tender offer, or otherwise; or
- removal of our incumbent officers and directors.

These provisions, as well as our ability to issue preferred stock, are designed to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased

protection give us the potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us, and that the benefits of this increased protection outweigh the disadvantages of discouraging those proposals, because negotiation of those proposals could result in an improvement of their terms.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol “CRGX.”

Transfer agent and registrar

The transfer agent and registrar for the common stock is Equiniti Trust Company, LLC. The transfer agent and registrar’s address is 6201 15th Avenue, Brooklyn, New York 11219.

Material U.S. federal income tax consequences to non-U.S. holders

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the Code), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the IRS), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a non-U.S. holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described in the subsection titled "—Sale or other taxable disposition" below.

Subject to the discussion below regarding effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption from withholding, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or other taxable disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (USRPI) by reason of our status as a U.S. real property holding corporation (USRPHC) for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to U.S. persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information reporting and backup withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the Non-U.S. Holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such

distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional withholding tax on payments made to foreign accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

Shares eligible for future sale

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common stock in the public market after the restrictions lapse. This may adversely affect the prevailing market price and our ability to raise equity capital in the future.

Based on the number of shares of our common stock outstanding as of June 30, 2023 and the 3,381,941 and 6,341,148 shares of our Series A-1 redeemable convertible preferred stock issued in the second tranche closing in July 2023 and the third tranche closing in October 2023, respectively, and assuming the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 18,836,559 shares of common stock and the related reclassification of the carrying value of the convertible preferred stock to permanent equity immediately prior to the completion of this offering, we will have 38,672,544 shares of common stock outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of any options after June 30, 2023. Of these shares, 18,750,000, or 21,562,500 shares of our common stock if the underwriters exercise their option to purchase additional shares in full, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining 19,922,544 shares of common stock outstanding will be "restricted shares" as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act, which rules are summarized below.

Rule 144

In general, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell such securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale; and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares of our common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume of shares of our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale,

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan

or other written agreement in compliance with Rule 701 before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) and who are not our "affiliates" as defined in Rule 144 during the immediately preceding 90 days, is entitled to rely on Rule 701 to resell such shares beginning 90 days after the date of this prospectus in reliance on Rule 144, but without complying with the notice, manner of sale, public information requirements or volume limitation provisions of Rule 144. Persons who are our "affiliates" may resell those shares beginning 90 days after the date of this prospectus without compliance with minimum holding period requirements under Rule 144 (subject to the terms of the lock-up agreement referred to below, if applicable).

Lock-up agreements

In connection with this offering, we, our directors, officers and substantially all of our securityholders have agreed with the underwriters that for a period of 180 days after the date of this prospectus, among other things and subject to certain exceptions more fully described under the section titled "Underwriting," not to sell or otherwise transfer or dispose of any of our securities during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior consent of J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC. See the section titled "Underwriting" for additional information.

Registration rights

Upon the completion of this offering, the holders of approximately 18,910,251 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described in the subsection titled "—Lock-up agreements" above. 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, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. The requisite percentage of these stockholders will waive all such stockholders' rights to notice of this offering and to include their shares of registrable securities in this offering. See the section titled "Description of capital stock—Registration rights."

Equity incentive plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under the 2021 Plan, the 2023 Plan and the ESPP. Such registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. Truist Securities, Inc. is also acting as a book-running manager of the offering. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	7,687,500
Jefferies LLC	5,390,625
Cowen and Company, LLC	3,984,375
Truist Securities, Inc.	1,687,500
Total	18,750,000

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.63 per share. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 2,812,500 additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $1.05 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per share	$ 1.05	$ 1.05
Total	$ 19,687,500	$ 22,640,625

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be

approximately $5.3 million. We have agreed to reimburse the underwriters for expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. in an amount up to $40,000.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not, subject to certain exceptions, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, hedge, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the SEC a registration statement under the Securities Act relating to, any shares of our common stock or any securities convertible into or exercisable or exchangeable for any shares of our common stock, or (ii) enter into any swap, hedging, or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any shares of common stock or any such other securities, or publicly disclose the intention to undertake any of the foregoing (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of RSUs (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing date of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; (iii) the issuance of up to 5% of the outstanding shares of common stock, or securities convertible into, exercisable for, or which are otherwise exchangeable for, common stock, immediately following the closing date of this offering, in acquisitions or other similar strategic transactions, provided that such recipients enter into a lock-up agreement with the underwriters; or (iv) the filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction.

Our directors, officers and substantially all of our securityholders (collectively, the lock-up parties) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the restricted period), may not and may not cause any of their direct or indirect affiliates to, without the prior written consent of J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including without limitation, our common stock or such other securities which may be deemed to be beneficially owned by the lock-up party in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) (collectively with the common

stock, the lock-up securities), (ii) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of the lock-up securities, in cash or otherwise, (iii) make any demand for or exercise any right with respect to the registration of any the lock-up securities, or (iv) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (whether by the lock-up party or any other person) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise. Such persons or entities further confirm that they have furnished the representatives with the details of any transaction such persons or entities, or any of their respective affiliates, is a party to as of the date hereof, which transaction would have been restricted by the lock-up agreements if it had been entered into by such persons or entities during the restricted period.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers, distributions, dispositions or surrenders of lock-up securities: (i) as bona fide gifts, or for bona fide estate planning purposes, (ii) by will, other testamentary documents or intestacy, (iii) to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, (iv) to a corporation, partnership, limited liability company or other entity of which the lock-up party and/or its immediate family members are the legal and beneficial owner of all of the outstanding equity securities or similar interests, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates or (B) as part of a distribution to partners, direct or indirect members, stockholders or other equityholders of the lock-up party; (vii) by operation of law, (viii) to us from an employee upon death, disability or termination of employment of such employee, (ix) as part of a sale or transfer of lock-up securities acquired in this offering or in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including “net” or “cashless” exercise), including for the payment of exercise price and tax and remittance payments, (xi) to us pursuant to any contractual arrangement in effect on the date of this prospectus and disclosed herein that provides for the repurchase of shares of our common stock in connection with the termination of the lock-up party’s employment with or service to us or (xii) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all stockholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in in this prospectus or filed as exhibits to our registration statement relating to this offering, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) the conversion of outstanding preferred stock, warrants to acquire preferred stock, or convertible securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrant received upon such conversion would be subject to restrictions

similar to those in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period.

J.P. Morgan Securities LLC, Jefferies LLC and Cowen and Company, LLC, in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Our common stock is listed on the Nasdaq Global Select Market under the symbol “CRGX.”

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount.

The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on Nasdaq, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;

- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Other relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

Notice to prospective investors in the United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA, provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a

prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to prospective investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority (DFSA). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the Dubai International Financial Centre (DIFC), this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to prospective investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to prospective investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the Corporations Act);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under Section 708 of the Corporations Act (Exempt Investors).

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under Section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in Section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any “resident” of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (ii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

Notice to prospective investors in Singapore

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

(i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or

(iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(i) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(1) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(2) where no consideration is or will be given for the transfer;

(3) where the transfer is by operation of law;

(4) as specified in Section 276(7) of the SFA; or

(5) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of the shares, the Company has determined, and hereby notifies all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to prospective investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to prospective investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the Company. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to prospective investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to prospective investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or the FETL. The shares have not been listed on any of the securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia, or Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital

Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to prospective investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, no “offer to the public” (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted), or the South African Companies Act) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a “registered prospectus” (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1)(a) the offer, transfer, sale, renunciation or delivery is to:

(i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;

(ii) the South African Public Investment Corporation;

(iii) persons or entities regulated by the Reserve Bank of South Africa;

(iv) authorized financial service providers under South African law;

(v) financial institutions recognized as such under South African law;

(vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or

(vi) any combination of the person in (i) to (vi), or

Section 96 (1) (b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as “advice” as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

Notice to prospective investors in Israel

In the State of Israel this prospectus supplement shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728–1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions, or the "Qualified Investors." The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. We have not and will not take any action that would require us to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus supplement or make, distribute or direct an offer to subscribe for our shares of common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered shares of common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued shares of common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968 (A) for its own account, (B) for investment purposes only, and (C) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

Legal matters

The validity of the issuance of the shares of common stock offered hereby will be passed upon for CARGO Therapeutics, Inc. by Latham & Watkins LLP, Menlo Park, California. Cooley LLP, San Francisco, California, is representing the underwriters.

Experts

The financial statements of Cargo Therapeutics, Inc. as of December 31, 2022 and 2021, and for each of the two years in the period ended December 31, 2022, included in this Prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

Where you can find more information

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock offered hereby. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to the company and our common stock, reference is made to the registration statement and the exhibits and any schedules filed therewith. Statements contained in this prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance, if such contract or document is filed as an exhibit, reference is made to the copy of such contract or other document filed as an exhibit to the registration statement, each statement being qualified in all respects by such reference. The SEC maintains a website at www.sec.gov, from which interested persons can electronically access the registration statement, including the exhibits and any schedules thereto.

As a result of the offering, we will be required to file periodic reports and other information with the SEC. We also maintain a website at www.cargo-tx.com, at which, following this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this prospectus or the registration statement of which it forms a part. We have included our website address as an inactive textual reference only.

Cargo Therapeutics, Inc.

Index to financial statements

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, 2022 and 2021, the related statements of operations and comprehensive loss, stockholders’ deficit, and cash flows, for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has sustained significant operating losses and negative cash flows since inception that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

San Francisco, California

September 1, 2023 (November 6, 2023, as to the effects of the reverse stock split described in Note 15)

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, 2021	December 31, 2022
Assets		
Current assets:		
Cash	$ 41	$ 1,872
Prepaid expenses and other current assets	143	2,055
Total current assets	184	3,927
Operating lease right-of-use asset	3,205	2,165
Property and equipment, net	673	3,368
Other non-current assets	442	783
Total assets	$ 4,504	$ 10,243
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 818	$ 3,483
Accrued clinical and research and development expenses	299	1,646
Accrued expenses and other current liabilities	394	3,391
Operating lease liability, current	938	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	2,449	44,137
Operating lease liability, non-current	2,230	1,092
Other non-current liabilities	—	250
Total liabilities	4,679	45,479
Commitments and contingencies (Note 6)		
Stockholders' deficit:		
Convertible preferred stock, $0.001 par value; 11,000,000 shares authorized at December 31, 2021 and 2022, respectively; 405,350 and 810,700 shares issued and outstanding at December 31, 2021 and 2022, respectively, (aggregate liquidation preference of $5,500 and $11,000 at December 31, 2021 and 2022, respectively)	1	1
Common stock, $0.001 par value; 25,433,526 and 29,000,000 shares authorized at December 31, 2021 and 2022, respectively; 810,699 and 1,091,800 shares issued and outstanding at December 31, 2021 and 2022, respectively	1	1
Additional paid-in capital	$ 5,871	$ 11,761
Accumulated deficit	(6,048)	(46,999)
Total stockholders' deficit	(175)	(35,236)
Total liabilities and stockholders' deficit	$ 4,504	$ 10,243

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, 2021	2022
Operating expenses:		
Research and development	$ 4,461	$ 29,373
General and administrative	1,516	5,398
Total operating expenses	5,977	34,771
Loss from operations	(5,977)	(34,771)
Interest expense	—	(4,942)
Change in fair value of derivative liabilities	—	(1,216)
Other income (expense), net	127	(22)
Net loss and comprehensive loss	$ (5,850)	$ (40,951)
Net loss per share attributable to common stockholders, basic and diluted	$ (38.38)	$ (104.40)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	152,422	392,268

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

Cargo Therapeutics, Inc.
Statements of stockholders' deficit

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances at January 1, 2021	**—**	**$ —**	**116,695**	**$ —**	**$ 2**	**$ (198)**	**$ (196)**
Issuance of Series Seed convertible preferred stock, net of issuance costs of $145	405,350	1	—	—	5,284	—	5,285
Issuance of Series Seed tranche commitment	—	—	—	—	70	—	70
Issuance of restricted stock awards	—	—	694,004	1	8	—	9
Stock-based compensation expense	—	—	—	—	507	—	507
Net loss	—	—	—	—	—	(5,850)	(5,850)
Balances at December 31, 2021	**403,350**	**1**	**810,699**	**1**	**5,871**	**(6,048)**	**(175)**
Issuance of Series Seed convertible preferred stock	405,350	—	—	—	5,500	—	5,500
Issuance of restricted stock awards	—	—	213,496	—	3	—	3
Vesting of restricted stock awards	—	—	—	—	18	—	18
Issuance of common shares for license	—	—	67,605	—	72	—	72
Stock-based compensation expense	—	—	—	—	297	—	297
Net loss	—	—	—	—	—	(40,951)	(40,951)
Balances at December 31, 2022	**810,700**	**$ 1**	**1,091,800**	**$ 1**	**$ 11,761**	**$ (46,999)**	**$ (35,236)**

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

Cargo Therapeutics, Inc.
Statements of cash flows

(in thousands)	Year ended December 31, 2021	2022
OPERATING ACTIVITIES		
Net loss	$(5,850)	$(40,951)
Adjustments to reconcile net loss to net cash used in operating activities:		
Noncash interest expense	—	4,942
Change in fair value of derivative liabilities	—	1,216
Amortization of operating lease right-of-use asset	130	1,040
Acquired in-process research and development	—	1,013
Depreciation	17	404
Stock-based compensation expense	507	297
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(143)	(1,912)
Other non-current assets	(442)	(267)
Accounts payable	332	2,819
Accrued clinical and research and development costs	299	1,222
Accrued expenses and other current liabilities	375	2,175
Operating lease liability	(167)	(1,070)
Net cash used in operating activities	(4,942)	(29,072)
INVESTING ACTIVITIES		
Purchase of property and equipment	(442)	(2,724)
Purchase of in-process research and development	—	(558)
Net cash used in investing activities	(442)	(3,282)
FINANCING ACTIVITIES		
Proceeds from issuance of convertible notes, net of issuance costs—related party	—	15,948
Proceeds from issuance of convertible notes, net of issuance costs	—	12,505
Proceeds from issuance of convertible preferred stock and tranche commitment, net of issuance costs	5,414	5,500
Proceeds from issuance of restricted stock awards	—	232
Net cash provided by financing activities	5,414	34,185
Net increase in cash	30	1,831
Cash, beginning of the year	11	41
Cash, end of the year	$ 41	$ 1,872
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES		
Purchase of property and equipment in accounts payable and accrued expenses and other current liabilities	$ 248	$ 623
In-process research and development costs in accounts payable, accrued expenses, other current liabilities and other non-current liabilities	$ —	$ 383
Deferred issuance costs for Series A-1 redeemable convertible preferred stock in accounts payable and accrued expenses and other current liabilities	$ —	$ 74
Issuance of shares in exchange for in-process research and development	$ —	$ 72

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 and trafficking to tumor lesions, 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.

Liquidity and going concern

Management is required to evaluate whether there are relevant conditions or events, when considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern and to meet its obligations as they become due within one year after the date the financial statements are issued.

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, 2022, the Company had an accumulated deficit of $47.0 million, cash of $1.9 million and negative cash flows from operations of $29.1 million. In February and July 2023, the Company issued and sold, primarily to existing and new investors, 5,072,919 shares and 3,381,941 shares, respectively, of its Series A-1 redeemable convertible preferred stock, resulting in aggregate net proceeds of $68.1 million and aggregate gross proceeds of $45.9 million, respectively. Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses and negative cash flows for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt regarding the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

The Company does not have any products approved for sale and has not generated any revenue from product sales since its inception. The Company does not expect to generate revenue from any product candidates that it

Cargo Therapeutics, Inc.
Notes to financial statements

develops until it obtains regulatory approval for one or more of such product candidates and commercialize its products or enters into collaboration agreements with third parties. The Company is seeking to complete an initial public offering ("IPO") of its common stock. In the event the Company does not complete an IPO, the Company expects to fund its operations through equity offerings or debt financings or other sources. There can be no assurance that the Company will be successful in raising additional funding. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to actively pursue its development programs and maintain their scope is dependent on obtaining sufficient funding on acceptable terms when needed and management of discretionary spending.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

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 deferred tax assets, the fair value of equity instruments, equity-based instruments, stock-based compensation, and the determination of the incremental borrowing rate.

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.

Cargo Therapeutics, Inc.
Notes to financial statements

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.

Concentration of credit risk and off-balance sheet risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash. Cash is deposited in checking and money market accounts at one financial institution, which at times may exceed federally insured limits. The Company has not experienced any losses historically in these accounts and believes it is not exposed to significant credit risk on its cash balances. The Company has no significant off-balance sheet concentrations of credit risk.

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:

Asset	Estimated useful life
Equipment and furniture	Three to five 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.

Cargo Therapeutics, Inc.
Notes to financial statements

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 7) 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.

Derivative liabilities

The Company's 2022 Convertible Notes contain certain embedded redemption features that are not clearly and closely related to the debt host instruments (see Note 7). 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.

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.

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.

Cargo Therapeutics, Inc.
Notes to financial statements

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. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable, otherwise, the Company uses its estimated collateralized incremental borrowing rate for the lease term. 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.

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

Research and development expenses represent direct and indirect costs incurred on the Company's development programs. These expenses include employee salaries, bonuses, benefits and stock-based compensation, third-party research and development expenses, including contract manufacturing and research services, consulting expenses, laboratory supplies, and certain allocated expenses, as well as amounts incurred under license agreements. 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 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.

Cargo Therapeutics, Inc.
Notes to financial statements

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.

Cargo Therapeutics, Inc.
Notes to financial statements

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, 2021 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 February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842), or ASC 842, which requires lessees to recognize leases on the balance sheet and disclose key information about leasing arrangements. ASC 842 establishes an ROU model that requires a lessee to recognize an ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement.

On January 1, 2021, the Company early adopted ASC 842 using the modified retrospective transition method and elected the package of practical expedients which permitted, which among other things, permits entities not to reassess: (i) whether any expired or existing contracts are or contain leases, (ii) lease classification for any expired or existing leases and, (iii) initial direct costs for any existing leases. Upon adoption of ASC 842 on January 1, 2021, the Company did not have any existing leases in place and the Company did not recognize any impact as a result of adoption, including no adjustment to the opening balance sheet or accumulated deficit.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 is effective for the Company beginning on January 1, 2022, with early adoption permitted. The Company adopted this standard on January 1, 2022. The adoption did not have a material impact on the Company's financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging— Contracts in Entity's Own Equity* (Subtopic 815-40): *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments by eliminating the requirement to separate embedded conversion features from the host contract when the conversion features are not required to be accounted for as derivatives under Topic 815, Derivatives

and Hedging, or that do not result in substantial premiums accounted for as paid-in capital. By removing the separation model, a convertible debt instrument will be reported as a single liability instrument with no separate accounting for embedded conversion features. This new standard also removes certain settlement conditions that are required for contracts to qualify for equity classification and simplifies the diluted earnings per share calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. The Company early adopted this standard on January 1, 2021. The adoption did not have a material impact on the Company's financial statements.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The amendments in ASU No. 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The Company adopted ASU 2021-04 on January 1, 2022. The adoption did not have a material impact on the Company's financial statements.

Recently issued accounting pronouncements not yet adopted

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.

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.

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On a recurring basis, the Company measures certain financial liabilities at fair value. The Company has no Level 1, 2 or 3 financial assets or liabilities carried at fair value as of December 31, 2021. There were no transfers between levels during the years ended December 31, 2021 and 2022. The following table summarizes the Company's financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

	December 31, 2022			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Liabilities:				
Derivative liabilities	$ —	$ —	$12,705	$12,705
Total financial liabilities	$ —	$ —	$12,705	$12,705

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 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 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 following table summarizes the significant inputs used in the valuation of the derivative liabilities:

	On issuance	**December 31, 2022**
Expected term to underlying triggering event (in years)	0.2 – 0.9	0.2 – 0.3
Probability of achievement of triggering event	0.0% – 95.0%	0.0% – 95.0%
Discount rate	74.4% – 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, 2022:

(in thousands)	**Derivative liabilities**
Balance as of January 1, 2022	$ —
Initial fair value of derivative liabilities	11,489
Change in fair value of derivative liabilities	1,216
Balance as of December 31, 2022	$ 12,705

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Financial commitment liabilities

The 2022 Convertible Notes included financial commitments to issue additional convertible notes to the noteholders in tranches (see Note 7). 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 8). 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%

4. Balance sheet components

Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
(in thousands)	2021	2022
Prepaid research and development	$108	$1,428
Other receivables	—	476
Prepaid other	35	151
Total prepaid expenses and other current assets	$143	$2,055

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Property and equipment, net

Property and equipment, net consisted of the following:

(in thousands)	December 31, 2021	December 31, 2022
Furniture and equipment	$255	$2,793
Leasehold improvements	17	105
Construction in progress	418	891
Property and equipment at cost	690	3,789
Less: accumulated depreciation	(17)	(421)
Property and equipment, net	$673	$3,368

Depreciation expense for the years ended December 31, 2021 and 2022 was $17,000 and $0.4 million, respectively.

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	December 31, 2021	December 31, 2022
Accrued compensation and related expenses	$294	$2,385
Accrued purchases of property and equipment	—	623
Other	100	383
Total accrued expenses and other current liabilities	$394	$3,391

5. Leases

In November 2021, the Company entered into a three-year operating lease for 15,400 square feet of lab and office space in San Mateo, California. The agreement provides one option to renew for one year, which the Company is not reasonably certain to exercise. The Company's variable lease cost is comprised primarily of the Company's proportionate share of operating expenses, property taxes and insurance as the Company elected not to separate lease and non-lease components. The Company paid $0.2 million in deposits upon execution of the lease which is recorded in other assets on the balance sheet. The Company is a sublessor in two agreements with initial terms of six months for a combined 2,300 square feet of the Company's leased premises. The future payments associated with the Company's operating lease liability as of December 31, 2022 were as follows:

(in thousands)	Amount
2023	$ 1,187
2024	1,147
Total undiscounted lease payments	2,334
Less: imputed interest	(236)
Total operating lease liability balance	$ 2,098

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A summary of total lease costs and other information for the periods relating to the Company's operating leases was as follows:

(in thousands)	Year ended December 31, 2021	2022
Operating lease cost	$183	$1,282
Variable lease cost	40	317
Short-term lease cost	88	—
Sublease income	—	(240)
Total lease cost	$311	$1,359

	December 31, 2021	2022
Other information:		
Remaining lease term (in years)	2.9	1.9
Discount rate	9.6%	9.6%

Supplemental cash flow and noncash information related to the Company's operating leases were as follows:

(in thousands)	Year ended December 31, 2021	2022
Cash flows from operating activities:		
Cash paid for amounts included in the measurement of lease liabilities	$ 220	$1,312
Right-of-use assets obtained in exchange for lease obligations:		
Total right-of-use assets capitalized	$3,335	$ —

The disclosures above exclude the lease of an additional premises of 15,717 square feet that was executed in August but had not yet commenced as of December 31, 2022. This additional lease expands the total leased premises at the Company's San Mateo, California headquarters to 31,117 square feet and commenced in February 2023. The total undiscounted lease payments related to this lease are $2.6 million, of which $1.3 million is due within 12 months.

6. 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 ("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, 2021 and 2022.

7. 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 12). 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 15) 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 as 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. As of December 31, 2022, the milestone for the third tranche had not been met. Subsequent to December 31, 2022, the third tranche for gross proceeds of $3.5 million was funded upon achieving the third milestone in January 2023 (see Note 15). 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-1 redeemable convertible preferred stock financing (see Note 15).

The 2022 Convertible Notes bear simple interest at 6.0% per annum. The principal and accrued interest can only be repaid prior to maturity upon consent of a majority of the investors or immediately upon demand.

The 2022 Convertible Notes are subject to automatic conversion upon the next financing whereby the Company issues 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 converts into the convertible preferred stock issued in the Qualified Financing at 75% of the lowest cash price per share. The 2022 Convertible Notes are 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) may 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 may choose to convert their 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 have 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 will 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 do 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 year ended December 31, 2022, $1.2 million in financial commitment liabilities were reclassified to the carrying amount of the respective convertible notes, and as of December 31, 2022, $0.7 million of financial commitment liabilities remained on the balance sheet, of which $0.4 million was associated with a related party.

Due to the conversion and redemption features embedded within the 2022 Convertible Notes, the Company bifurcated compound derivative liabilities related to all tranches funded through to December 31, 2022 (see Note 3). The aggregate fair value at issuance of the derivative liabilities was $11.5 million and is 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 is amortized using the effective interest rate method over the term of the respective note. For the year ended December 31, 2022, the Company recognized $4.9 million of interest expense, including accrued interest, amortization of the debt discount and amortization of debt issuance costs, in the statement of operations and comprehensive loss.

8. Convertible preferred stock

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

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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.

Convertible preferred stock consisted of the following:

	December 31, 2021				
(in thousands, except shares and per share amounts)	Shares authorized	Shares issued and outstanding	Original issue price	Liquidation preference	Carrying value
Series Seed	11,000,000	405,350	$ 13.57	$ 5,500	$ 5,285
Total	11,000,000	405,350		$ 5,500	$ 5,285

	December 31, 2022				
(in thousands, except shares and per share amounts)	Shares authorized	Shares issued and outstanding	Original issue price	Liquidation preference	Carrying value
Series Seed	11,000,000	810,700	$ 13.57	$ 11,000	$ 10,855
Total	11,000,000	810,700		$ 11,000	$ 10,855

The holders of convertible preferred stock have various rights, preferences and privileges as follows:

Voting rights

The holders of convertible preferred stock shares are entitled to vote on all matters on which the common stockholders are entitled to vote. Holders of convertible preferred and common stock vote together as a single class, not as separate classes. Each holder of convertible preferred stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares held by such holder are convertible. Holders of shares of convertible preferred stock are entitled to elect two directors of the Company. Holders of shares of common stock are entitled to elect three directors of the Company. Holders of convertible preferred stock and common stock, voting together as a single class on an as-converted basis, are entitled to elect the balance of the total number of directors of the Company.

As long as any convertible preferred stock shares remain outstanding, the Company must obtain approval from a majority of the holders of the then outstanding shares of convertible preferred stock to alter or change the rights, preferences and privileges of convertible preferred stock, change the authorized number of convertible preferred and common stock, create a new class or series of shares having any rights, preferences or privileges superior to or on parity with any outstanding shares of convertible preferred stock, declare or pay any distribution, merge, consolidate with or implement a reorganization that would result in the transfer of 50% of the voting power of the Company, sell all or substantially all of the Company's assets, voluntarily dissolve or liquidate the Company, change the authorized number of directors, incur indebtedness greater than $0.3 million and appoint or remove the chief executive officer.

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Dividends

The Company's certificate of incorporation permits the holders of shares of convertible preferred stock to receive, only when, as and if declared by the Board of Directors, dividends at a rate of 8% of the applicable original issue price of $13.57 per share, as adjusted for stock dividend, stock split, combination or other similar recapitalization (the "Original Issue Price"), prior and in preference to any declaration or payment of any other dividend (other than dividends on shares of common stock payable in common stock). Such dividends are non-cumulative. The Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company (other than dividends on shares of common stock payable in common stock) unless the holders of convertible preferred stock then outstanding shall first receive, or simultaneously received, in addition to the 8% dividend noted above, an equal dividend on an as converted basis, if the dividend is declared on common stock or securities convertible in common stock. If the dividend is declared on non-common stock or securities not convertible in common stock, the holders of convertible preferred stock then outstanding must also receive an equal dividend to the dividend of such class, divided by its issuance price and multiplied by the applicable Original Issue Price, provided that if the Company declares a dividend on the same date on shares on more than one class or series of stock the dividend payable to the convertible preferred stockholders shall be based on the dividend on the class or series that would result in the highest preferred dividend. No dividends were declared as of December 31, 2021 and 2022.

Liquidation

In the event of any liquidation, dissolution 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 of consolidation, or the sale of substantially all of the assets 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, the holders of convertible preferred stock will receive in preference to any distribution of assets to the holders of common stock, an amount per share equal the Original Issue Price, plus any declared and unpaid dividends. If the assets available for distribution are insufficient then proceeds will be distributed ratably among the holders of convertible preferred stock in proportion to the full preferential amount that each such holder is entitled to receive. If there are remaining assets of the Company legally available for distribution after the payment of the full liquidation preference of the convertible preferred stock, those remaining assets shall be distributed ratably to the holders of common stock and convertible preferred stock on an as-if-converted to common stock basis, provided however that if the aggregate amount which the holders of convertible preferred stock are entitled to receive shall exceed $40.71 per share, then the holder of convertible preferred stock will receive an amount per share equal to the greater of (i) $40.71 and (ii) the amount that would have been payable if all shares of convertible preferred stock had been converted into common stock immediately prior to the liquidation event.

Conversion

Each share of convertible preferred stock is convertible, at the option of the holder, into the number of shares of common stock into which such shares are convertible at the then-effective conversion ratio. The conversion ratio is determined by dividing the applicable Original Issue Price by the then applicable conversion price. The initial conversion price per share for convertible preferred stock is the Original Issue price of $13.57 per share.

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The initial conversion price is subject to adjustment from time to time. Each share of convertible preferred stock shall automatically be converted into fully-paid, non-assessable shares of common stock at the then-effective conversion rate for such share (i) immediately prior to the closing of a firm commitment underwritten IPO pursuant to an effective registration statement filed under the Securities Act of 1933, as amended, covering the offer and sale of the Company's common stock, provided that the offering price per share is not less than $67.85 (as adjusted for stock dividend, stock split, combination or other similar recapitalization) and the aggregate gross proceeds to the Company are not less than $75.0 million, or (ii) at the date and time, or occurrence, of an event specified in a vote or written consent of the holders of the majority of the outstanding shares of convertible preferred stock.

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 of 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. These redemption events were deemed to be within the control of the Company, and all shares of convertible preferred stock have accordingly been presented within permanent equity.

9. 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, subject to prior rights of the convertible preferred stockholders. Common stock issued and outstanding on the balance sheets and statements of stockholders' 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,	
	2021	2022
Convertible preferred stock	405,350	810,700
Common stock options issued and outstanding under the Plan	—	167,882
Remaining shares available for issuance under the Plan	187,445	22,928
Total reserved common stock	592,795	1,001,510

The 2022 Convertible Notes, which are excluded from the table above, converted into shares of Series A-2 redeemable convertible preferred stock subsequent to December 31, 2022 (see Note 15).

10. Stock-based compensation

2021 stock option and grant plan

In July 2021, the Company established its 2021 Stock Option and Grant Plan (the "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. Options granted under the Plan may be either incentive stock

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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 number of shares of common stock available for issuance under the Plan may be increased from time to time by the Board of Directors. In 2022, the Board of Directors amended shares authorized for issuance under the Plan. As of December 31, 2022, shares authorized for issuance under the Plan were 393,268.

The exercise price of an ISO and NSO shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the Board of Directors. 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 estimated fair value of the shares on the date of grant, as determined by the Board of Directors. To date, options have a term of ten years and generally vest over a four-year period.

Stock options

Stock option activity for year ended December 31, 2022 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, 2021	—	$ —	—	$ —
Granted	167,882	$ 1.09		
Outstanding at December 31, 2022	167,882	$ 1.09	9.65	$ —
Vested and expected to vest, December 31, 2022	167,882	$ 1.09	9.65	$ —
Exercisable at December 31, 2022	71,931	$ 1.09	9.77	$ —

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, 2022.

The estimated weighted-average grant-date fair value of options granted during the year ended December 31, 2022 was $0.79 per share. As of December 31, 2022, there was $0.1 million of unrecognized stock-based compensation related to stock options, which is expected to be recognized over a weighted-average period of 3.2 years.

The Company did not grant any stock options as of and prior to December 31, 2021.

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 equal to lower of (i) the fair market value on the date of repurchase or (ii) their original purchase price no later than six 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.

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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 conjunction with the closing of the first closing of the Series Seed convertible preferred stock in February 2021, the Company entered into restricted stock agreements with the principal owners and directors of the Company (the "Founders") to grant 694,004 shares of restricted stock awards to the Founders (the "Founder Awards"). Under the Founder restricted stock agreements, 472,906 shares of the Founder Awards vest based on continuous service (the "Service Awards") and 221,098 shares vest based on both continuous service and achievement of performance conditions (the "Performance Awards"). All unvested shares were subject to repurchase by the Company upon termination of continuous service at a repurchase price equal to lower of (i) the fair market value on the date of repurchase or (ii) their original purchase price. As the Founder Awards vest based on continuous service, the Founder Awards were accounted as a compensatory arrangement under *ASC Topic 718, Compensation-Stock Compensation* ("ASC 718"). The Company determined that the service condition of the Founder Awards was not substantive and immediately expensed $0.5 million, the grant date fair value of the Service Awards on issuance in February 2021. For the Performance Awards, the Company determined that achievement of the performance condition was not probable as of December 31, 2021 and did not recognize any stock-based compensation expense for these awards for the year ended December 31, 2021.

In April 2022, the Performance Awards were modified to remove the performance condition 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, 2021	586,564	$	1.08
Issued	213,496		0.65
Vested	(270,950)		1.04
Unvested as of December 31, 2022	529,110	$	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 $8,000 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, 2021 and 2022, respectively. No restricted stock awards were repurchased or cancelled during the years ended December 31, 2021 and 2022.

As of December 31, 2022, 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 of 3.1 years.

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Stock-based compensation expense

Total stock-based compensation expense recorded in the statements of operations and comprehensive loss was as follows:

(in thousands)	Year ended December 31, 2021	2022
General and administrative	$ 426	$ 217
Research and development	81	80
Total stock-based compensation expense	$ 507	$ 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—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.

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—For all stock awards granted to date, the volatility data was estimated based on a study of publicly traded industry peer companies. To identify 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 has no history or expectation of paying cash dividends on its 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.

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The estimated grant-date fair value of awards granted was calculated based on the following assumptions:

	Year ended December 31,	
	2021	2022
Expected term (in years)	3.6	2.8 – 6.1
Expected volatility	97.1%	84.6% – 89.8%
Expected dividend	—	—
Risk-free interest rate	0.3%	3.0% – 4.7%

11. 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 Agreement"). Pursuant to the Stanford License Agreement, 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.

As consideration for the licenses granted under the Stanford License Agreement, 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 Agreement represented an asset acquisition as it did not meet the definition of a business. As the acquired licenses represented 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 Agreement.

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 that achieves specific clinical trials or regulatory approvals, up to $0.6 million in milestone payments upon achievement of commercial milestone events and double-digit percentage milestone payments on non-patented products and, subject to certain royalty reductions, low single-digit percentage royalties on net sales of products. Subject to the terms of the Stanford License Agreement, the Company also agreed to pay Stanford University a certain percentage of non-royalty sublicense-related revenue that the Company may receive from third-party sublicensees.

Crystal Mackall and Robbie Majzner, who were the Company's principal owners and directors when the Company entered into the license agreement, 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

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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 may be required to pay up to $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 Agreement”) 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-sublicenseable 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.

As consideration for the licenses granted under the 2022 NCI License Agreement, the Company is required to pay NCI a non-refundable license fee of $0.6 million, of which $0.2 million was paid in 2022, and the remaining balance of $0.4 million is payable in three equal annual installments beginning on the first anniversary of the effective date of the agreement. The Company determined that the purchase of the license under the 2022 NCI License 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 initial consideration of $0.6 million under the 2022 NCI License Agreement as research and development expense in March 2022, upon entering into the 2022 NCI License Agreement. The Company accrued the non-refundable fees of $0.4 million payable upon entering into the 2022 NCI License Agreement of which $0.3 million is classified as other non-current liabilities on the balance sheet as of December 31, 2022.

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 at a low single-digit percentage, depending on the amount of annual net sales and subject to the terms of the 2022 NCI License Agreement. 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 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 NCI a percentage of the fair market value of the consideration the Company receives for any assignment of the 2022 NCI License Agreement to a non-affiliate (upon NCI's prior written consent) or an allocated portion of the fair value of consideration received in connection with a change in control.

NCI may terminate or modify the 2022 NCI License Agreement 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 NCI.

12. 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.

Apart from the transactions and balances detailed in Note 7 and Note 11, the Company has no other significant or material related party transactions during the years ended December 31, 2022 and 2021.

13. Income taxes

The loss before provision for income taxes for the years ended December 31, 2021 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, 2021 and 2022.

The reconciliation of the effective tax rate for income taxes from the federal statutory rate were as follows:

	Year ended December 31,	
	2021	2022
U.S. federal taxes at statutory rate	21.0%	21.0%
State tax – net of federal	1.8	(1.8)
Federal tax credits	—	7.8
Change in valuation allowance	(21.2)	(23.4)
Stock-based compensation	—	(0.1)
Non-deductible expenses	(0.7)	(3.2)
Other	(0.9)	(0.3)
Total	—%	—%

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The income tax effect of temporary differences that give rise to significant portions of the Company's deferred tax assets at December 31, 2021 and 2022 is presented below:

(in thousands)	December 31, 2021	December 31, 2022
Deferred tax assets:		
Depreciation and amortization	$ (52)	$ 1,220
Capitalized research and development costs	—	6,009
Net operating loss carryforwards	560	1,244
Accrued expenses and other current liabilities	730	97
Operating lease liabilities	680	441
Tax credit carryforwards	83	2,350
Right of use assets	(688)	(465)
Stock-based compensation	—	3
Total net deferred tax assets	1,313	10,899
Less: valuation allowance	(1,313)	(10,899)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company has net operating loss carryforwards of approximately $5.9 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, 2021 and 2022 was $1.2 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, 2022, the Company has Federal and California research and development credit carryforwards of $1.8 million and $1.7 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 has not conducted an analysis and the Company may have experienced ownership changes in the past or may experience the change in the future.

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A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	December 31,	
(in thousands)	**2021**	**2022**
Balance at the beginning of the year	$ —	$ 35
Increases based on tax positions related to current year	35	837
Balance at end of year	$ 35	$ 872

As of December 31, 2022, the Company had $0.9 million of unrecognized tax benefits which are comprised of federal of $0.5 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, 2021, 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.

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,	
(in thousands, except share and per share amounts)	**2021**	**2022**
Numerator:		
Net loss attributable to common stockholders	$ (5,850)	$ (40,951)
Denominator:		
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	152,422	392,268
Net loss per share attributable to common stockholders, basic and diluted	$ (38.38)	$ (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,	
	2021	**2022**
Convertible preferred stock, as converted	405,350	810,700
2022 Convertible Notes, as converted	—	2,870,397
Outstanding stock options	—	167,882
Restricted stock awards subject to repurchase	586,564	529,110
Total	991,914	4,378,089

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15. Subsequent events

Management has reviewed and evaluated material subsequent events from the balance sheet date of December 31, 2022 through September 1, 2023, the day the financial statements were available for issuance, and November 6, 2023 for the reverse stock split discussed below.

Issuance of convertible notes

In January 2023, the third tranche of the convertible note purchase agreement executed in October 2022 (see Notes 3 and 7) was issued for gross proceeds of $3.5 million, including $2.2 million issued to a related party. The Company allocated a portion of the proceeds to an embedded derivative liability at fair value of $2.1 million, creating a debt discount to the convertible note to be amortized using the effective interest rate method. The Company reclassified the outstanding financial commitment liabilities of $0.7 million to the carrying amount of the third tranche of the convertible note.

Series A redeemable convertible preferred stock financing

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 is obligated to issue and sell shares of its redeemable convertible preferred stock for $13.57 per share immediately at execution and through a second and third tranche. In February 2023, the Company issued 5,072,919 shares of its Series A-1 redeemable convertible preferred stock as part of the first tranche and received aggregate net proceeds of approximately $68.1 million.

Pursuant to the Series A Agreement, through the second tranche, the Company is obligated to sell 3,381,941 shares of its Series A-1 redeemable convertible preferred stock upon satisfaction of certain developmental milestones by the end of the third quarter of 2023. For the third tranche, the Company is obligated to sell 6,341,148 shares of its Series A-1 redeemable convertible preferred stock upon the satisfaction of certain developmental milestones by the middle of the first quarter of 2024.

Concurrent with the closing of the Series A-1 redeemable convertible preferred stock, the Company amended the terms of the 2022 Convertible Notes to convert those notes into shares of the Company's Series A-2 redeemable convertible preferred stock at a conversion price of $10.18 per share. The $32.9 million in outstanding principal and accrued interest was converted into 3,229,851 shares of Series A-2 redeemable convertible preferred stock, of which $18.7 million related to a related party converted into 1,833,623 shares.

Upon closing of the first tranche of shares of Series A-1 redeemable convertible preferred stock and conversion of the 2022 Convertible Notes to shares of Series A-2 redeemable convertible preferred stock, the redeemable convertible preferred stockholders collectively have 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 Series Seed convertible preferred stock (see Note 9) is no longer within the control of the Company. In accordance with ASC 480, *Distinguishing Liabilities from Equity*, equity instruments with redemption features that are not solely within the control of the issuer must be classified outside of permanent equity. Accordingly, all shares of Series Seed convertible preferred stock were reclassified from permanent equity to mezzanine equity prospectively.

In July 2023, pursuant to the Series A Agreement, upon satisfaction of certain developmental milestones, the Company issued and sold 3,381,941 shares of its Series A-1 redeemable convertible preferred stock as part of the second tranche and received aggregate gross proceeds of approximately $45.9 million.

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Amendment and restatement of certificate of incorporation

In conjunction with the Series A redeemable convertible preferred stock financing, in February 2023, the Company amended and restated its Certificate of Incorporation to increase the authorized shares of common stock to 320,000,000 shares and to authorize issuable shares of Series A-1 and Series A-2 redeemable convertible preferred stock of 200,760,000 and 43,824,255 shares, respectively. The Company also amended the election of the Board of Directors in the Certificate of Incorporation. The holders of Series A redeemable convertible preferred stock are entitled to elect two directors. Prior to the closing of the third tranche of Series A-1 redeemable convertible preferred stock, the holders of Series Seed convertible preferred stock are entitled to elect two directors. Subsequent to the closing of the third tranche of Series A-1 redeemable convertible preferred stock, the holders of Series Seed convertible preferred stock are entitled to elect one director. The holders of common stock are entitled to elect one director and one director will be the Company's Chief Executive Officer. The remaining two directors will be independent directors that are elected by stockholder vote and must be mutually acceptable to the other directors.

Additionally, the Company amended the Plan to increase the shares reserved and available for issuance under the Plan from 393,268 to 3,268,399 shares.

2023 NCI license agreement

In February 2023, the Company entered into an exclusive license agreement (the "2023 NCI License Agreement") with NCI, pursuant to which the Company obtained to acquire a worldwide, royalty-bearing, exclusive license under certain patent rights to research, develop and commercialize products covered by such licensed patents owned by 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 both: receptors targeting CD19, CD20, and/or CD79b; and using STASH platform and/or a technology to activate CD2 signaling in the CAR T cell.

As consideration for the licenses granted under the 2023 NCI License Agreement, the Company must pay 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 NCI for $0.1 million in expenses incurred by 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 Agreement.

The Company agreed to pay up to $0.1 million in regulatory milestone payments upon achieving 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 Agreement, 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 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 NCI a percentage of the fair market value of the consideration the Company receives for any assignment of the 2023 NCI License Agreement to a non-affiliate (upon NCI's prior

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written consent) or an allocated portion of the fair value of consideration received in connection with a change in control.

Unless earlier terminated, the 2023 NCI License Agreement will expire upon the expiration of the last to expire licensed patent right. NCI may terminate or modify the 2023 NCI License Agreement 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 NCI.

Silicon Valley Bank

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. The balance of the Company's cash accounts at SVB was $62.6 million at the time of SVB's closure. The Company received access to all of its cash on March 13, 2023. The Company has since diversified the financial institutions where its cash and money market accounts are held.

Grant of stock options

In April and August 2023, the Company granted options for 1,985,027 and 1,078,806 shares of the Company's common stock to its employees, with exercise prices of $5.03 and $9.50 per share, respectively.

Amendment to the Plan

In July 2023, the Company amended the Plan to increase shares reserved and available for issuance under the Plan from 3,268,399 to 3,618,904 shares.

Reverse Stock Split

In November 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 convertible preferred stock on a 13.5685-for-1 basis (the "Reverse Stock Split"), which was effected on November 3, 2023. The authorized shares and the par value of the common stock and convertible preferred stock were not adjusted as a result of the Reverse Stock Split. Accordingly, all share data and per share data amounts for all periods presented in the financial statements and notes thereto have been retrospectively adjusted to reflect the effect of the Reverse Stock Split.

Cargo Therapeutics, Inc.
Condensed balance sheets

(in thousands, except share and per share data)	December 31, 2022 (Note 2)	June 30, 2023 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 1,872	$ 42,371
Prepaid expenses and other current assets	2,055	2,351
Redeemable convertible preferred stock tranche asset	—	2,016
Total current assets	3,927	46,738
Operating lease right-of-use asset	2,165	3,413
Property and equipment, net	3,368	5,912
Other non-current assets	783	4,434
Total assets	$ 10,243	$ 60,497
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,483	$ 5,822
Accrued clinical and research and development expenses	1,646	6,677
Accrued expenses and other current liabilities	3,391	3,088
Operating lease liabilities, current	1,006	2,495
Redeemable convertible preferred stock tranche liability	—	10,025
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	44,137	28,107
Operating lease liabilities, non-current	1,092	978
Other non-current liabilities	250	225
Total liabilities	45,479	29,310
Redeemable convertible preferred stock, $0.001 par value; 255,584,255 shares authorized and 9,113,470 shares issued and outstanding at June 30, 2023, respectively, (aggregate liquidation preference of $112,700 at June 30, 2023)	—	106,166
Stockholders' 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; 29,000,000 and 320,000,000 shares authorized at December 31, 2022 and June 30, 2023, respectively; 1,091,800 and 1,085,985 shares issued and outstanding at December 31, 2022 and June 30, 2023, respectively	1	1
Additional paid-in capital	11,761	2,618
Accumulated deficit	(46,999)	(77,598)
Total stockholders' deficit	(35,236)	(74,979)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 10,243	$ 60,497

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

Cargo Therapeutics, Inc.
Condensed statements of operations and comprehensive loss

(in thousands, except share and per share data) (unaudited)	Six months ended June 30, 2022	2023
Operating expenses:		
Research and development	$ 11,673	$ 26,491
General and administrative	2,044	6,552
Total operating expenses	13,717	33,043
Loss from operations	(13,717)	(33,043)
Interest expense	(776)	(1,604)
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	(692)
Change in fair value of derivative liabilities	(407)	6,453
Loss on extinguishment of convertible notes	—	(2,316)
Other income (expense), net	(17)	603
Net loss and comprehensive loss	$ (14,917)	$ (30,599)
Net loss per share attributable to common stockholders, basic and diluted	$ (50.01)	$ (48.21)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	298,296	634,704

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

Cargo Therapeutics, Inc.
Condensed statements of stockholders' deficit

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balances at January 1, 2022	**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	—	—	139,649	—	2	—	2
Stock-based compensation expense	—	—	—	—	241	—	241
Net loss	—	—	—	—	—	(14,917)	(14,917)
Balances at June 30, 2022	**810,700**	**$ 1**	**950,348**	**$ 1**	**$ 11,614**	**$ (20,965)**	**$ (9,349)**

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

Cargo Therapeutics, Inc.
Condensed statements of redeemable convertible preferred stock and stockholders' deficit

	Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at January 1, 2023	**— $**	**—**	**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 $755 and redeemable convertible preferred stock tranche obligations of $7,317	5,072,919	60,760	—	—	—	—	—	—	—
Issuance of Series A-2 redeemable convertible preferred stock upon conversion of convertible notes	3,229,851	35,576	—	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	1,695	—	2	—	2
Issuance of restricted stock awards	—	—	—	—	1,874	—	—	—	—
Vesting of restricted stock awards	—	—	—	—	—	—	61	—	61
Repurchase of restricted stock awards	—	—	—	—	(9,384)	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	623	—	623
Net loss	—	—	—	—	—	—	—	(30,599)	(30,599)
Balances at June 30, 2023	**9,113,470 $**	**106,166**	**— $**	**—**	**1,085,985 $**	**1**	**$ 2,618**	**$ (77,598)**	**$ (74,979)**

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

Cargo Therapeutics, Inc.
Condensed statements of cash flows

(in thousands) (unaudited)	Six months ended June 30, 2022	2023
OPERATING ACTIVITIES		
Net loss	$(14,917)	$(30,599)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of convertible notes	—	2,316
Amortization of operating lease right-of-use asset	527	1,043
Noncash interest expense	776	1,604
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	692
Acquired in-process research and development	850	466
Stock-based compensation expense	241	623
Depreciation	125	499
Change in fair value of derivative liabilities	407	(6,453)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,176)	(296)
Other non-current assets	(100)	(3,836)
Accounts payable	2,887	1,384
Accrued clinical and research and development expenses	1,387	5,031
Accrued expenses and other current liabilities	215	(523)
Operating lease liabilities	(468)	(916)
Net cash used in operating activities	(9,246)	(28,965)
INVESTING ACTIVITIES		
Purchase of property and equipment	(1,185)	(2,054)
Purchase of in-process research and development	(257)	(59)
Net cash used in investing activities	(1,442)	(2,113)
FINANCING ACTIVITIES		
Proceeds from issuance of convertible notes, net of issuance costs—related party	6,354	2,212
Proceeds from issuance of convertible notes, net of issuance costs	5,636	1,286
Proceeds from issuance of convertible preferred stock and tranche commitment, net of issuance costs	5,500	—
Proceeds from issuance of redeemable convertible preferred stock and tranche obligations, net of issuance costs	—	68,077
Proceeds from exercise of stock options	—	2
Net cash provided by financing activities	17,490	71,577
Net increase in cash and cash equivalents	6,802	40,499
Cash and cash equivalents at beginning of period	41	1,872
Cash and cash equivalents at end of period	$ 6,843	$ 42,371

Cargo Therapeutics, Inc.
Condensed statements of cash flows—(Continued)

(in thousands) (unaudited)	Six months ended June 30, 2022	 2023
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES		
Conversion of convertible notes to shares of Series A-2 redeemable convertible preferred stock	$ —	$35,576
Reclassification of shares of Series Seed redeemable convertible preferred stock to mezzanine equity	$ —	$ 9,830
Purchase of property and equipment in accounts payable, accrued expenses and other current liabilities	$279	$ 1,612
In-process research and development costs in accounts payable, accrued expenses, other current liabilities and other non-current liabilities	$593	$ 790
Deferred offering costs related to initial public offering included in accounts payable, accrued expenses and other current liabilities	$ —	$ 218
Deferred issuance costs for the second tranche of Series A-1 redeemable convertible preferred stock in accounts payable, accrued expenses and other current liabilities	$ —	$ 33
Convertible notes payable issuance costs in accounts payable, accrued expenses and other current liabilities	$ 27	$ —

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

Cargo Therapeutics, Inc.
Notes to unaudited condensed 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 and trafficking to tumor lesions, 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.

Liquidity and going concern

Management is required to evaluate whether there are relevant conditions or events, when considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern and to meet its obligations as they become due within one year after the date the financial statements are issued.

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 six months ended June 30, 2023, the Company had an accumulated deficit of $77.6 million, cash and cash equivalents of $42.4 million and negative cash flows from operations of $29.0 million. In July 2023, the Company issued and sold, primarily to existing and new investors, 3,381,941 shares of its Series A-1 redeemable convertible preferred stock, resulting in aggregate gross proceeds of $45.9 million. Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, the Company has concluded that there is substantial doubt regarding the Company's ability to continue as a going concern within one year after the date that these financial statements are issued.

The Company does not have any products approved for sale and has not generated any revenue from product sales since its inception. The Company does not expect to generate revenue from any product candidates that it develops until it obtains regulatory approval for one or more of such product candidates and commercialize its

Cargo Therapeutics, Inc.
Notes to unaudited condensed financial statements

products or enters into collaboration agreements with third parties. The Company is seeking to complete an initial public offering ("IPO") of its common stock. In the event the Company does not complete an IPO, the Company expects to fund its operations through equity offerings or debt financings or other sources. There can be no assurance that the Company will be successful in raising additional funding. As a result, the Company has concluded that management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to actively pursue its development programs and maintain their scope is dependent on obtaining sufficient funding on acceptable terms when needed and management of discretionary spending.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

2. Summary of significant accounting policies

Basis of presentation

The Company has prepared the accompanying condensed financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") and the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. 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, 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.

Unaudited interim condensed financial statements

The interim condensed balance sheet as of June 30, 2023 and the interim condensed statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the six months ended June 30, 2022 and 2023 are unaudited. These unaudited interim condensed financial

Cargo Therapeutics, Inc.
Notes to unaudited condensed financial statements

statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair statement of the Company's financial position, results of operations and cash flows for the interim periods presented. The condensed results of operations for the six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the full year or for any other future annual or interim period. The condensed balance sheet as of December 31, 2022 included herein was derived from the audited financial statements as of that date. These interim condensed financial statements should be read in conjunction with the Company's audited financial statements included elsewhere in this prospectus.

Cash and cash equivalents

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.

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.

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 issuance 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.

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.

Cargo Therapeutics, Inc.
Notes to unaudited condensed financial statements

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 or extinguishment.

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

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 and cash equivalents, 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.

Cargo Therapeutics, Inc.
Notes to unaudited condensed financial statements

On a recurring basis, the Company measures certain financial liabilities at fair value. There were no transfers between levels during the six months ended June 30, 2023 and year ended December 31, 2022. The following tables summarize the Company's financial assets and financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

	December 31, 2022			
(in thousands)	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative liabilities	$ —	$ —	$12,705	$12,705
Total financial liabilities	$ —	$ —	$12,705	$12,705

	June 30, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$38,790	$ —	$ —	$38,790
Redeemable convertible preferred stock tranche asset	—	—	2,016	2,016
Total financial assets	$38,790	$ —	$ 2,016	$40,806
Liabilities:				
Redeemable convertible preferred stock tranche liability	$ —	$ —	$10,025	$10,025
Total financial liabilities	$ —	$ —	$10,025	$10,025

Derivative liabilities

In April and October 2022, the Company executed convertible note purchase agreements with its existing investors (see Note 6). 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).

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Notes to unaudited condensed financial statements

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 summarizes the changes in the derivative liabilities:

(in thousands)	Derivative liabilities
Balance as of December 31, 2022	$ 12,705
Additions[1]	2,133
Change in fair value	(6,453)
Settlement	(8,385)
Balance as of June 30, 2023	$ —

(1) The additions to derivative liabilities in the six months ended June 30, 2023 relate to the embedded derivative bifurcated from the final tranche of the 2022 Convertible Notes that was issued in January 2023.

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. The redeemable convertible preferred stock tranche obligations are considered a contingent forward and the standard forward pricing model was used with the following key assumptions:

	Redeemable convertible preferred stock tranche asset		Redeemable convertible preferred stock tranche liability	
	On issuance date February 9, 2023	As of June 30, 2023	On issuance date February 9, 2023	As of June 30, 2023
Expected term to achievement of milestone (in years)	0.4	—	0.8	0.4
Probability of achievement of milestone	90.0%	97.5%	63.0%	68.3%
Discount rate	4.9%	5.5%	4.9%	5.5%

Cargo Therapeutics, Inc.
Notes to unaudited condensed financial statements

The following table summarizes the changes in the fair value of the redeemable convertible preferred stock tranche asset and liability:

(in thousands)	Redeemable convertible preferred stock tranche asset	Redeemable convertible preferred stock tranche liability
Balance as of December 31, 2022	$ —	$ —
Initial recognition	1,788	(9,105)
Change in fair value	228	(920)
Balance as of June 30, 2023	$ 2,016	$ (10,025)

4. Balance sheet components

Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

(in thousands)	December 31, 2022	June 30, 2023
Prepaid research and development	$ 1,428	$ 1,794
Other receivables	476	475
Prepaid other	151	82
Total prepaid expenses and other current assets	$ 2,055	$ 2,351

Property and equipment, net

Property and equipment, net consisted of the following:

(in thousands)	December 31, 2022	June 30, 2023
Furniture and equipment	$ 2,793	$ 6,388
Leasehold improvements	105	105
Construction in progress	891	339
Property and equipment at cost	3,789	6,832
Less: accumulated depreciation	(421)	(920)
Property and equipment, net	$ 3,368	$ 5,912

Depreciation expense for the six months ended June 30, 2022 and 2023 was $0.1 million and $0.5 million, respectively.

Cargo Therapeutics, Inc.
Notes to unaudited condensed financial statements

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	December 31, 2022	June 30, 2023
Accrued compensation and related expenses	$ 2,385	$ 1,426
Accrued purchases of property and equipment	623	623
Other	383	1,039
Total accrued expenses and other current liabilities	$ 3,391	$ 3,088

5. Leases

In November 2021, the Company entered into a three-year operating lease for 15,400 square feet of lab and office space in San Mateo, California. The agreement provides for one option to renew for one year which the Company is not reasonably certain to exercise. In February 2023, the operating lease commenced for an additional premises for 15,717 square feet of lab and office space, increasing the total leased premises to 31,117 square feet at the existing San Mateo, California location. The new lease has a term of two years. The Company paid an additional $0.3 million in deposits upon commencement of the new lease which is recorded in other assets on the balance sheet. The Company is a sublessor in two agreements with initial terms of six months for a combined 2,300 square feet of the Company's leased premises. The future payments associated with the Company's operating lease liabilities as of June 30, 2023 were as follows:

(in thousands)	Amount
2023 (remaining six months)	$ 1,367
2024	2,404
Total undiscounted lease payments	3,771
Less: imputed interest	(298)
Total operating lease liabilities	$ 3,473

A summary of total lease costs and other information for the periods relating to the Company's operating leases was as follows:

	Six months ended June 30,	
(in thousands)	2022	2023
Operating lease cost	$636	$1,246
Variable lease cost	160	308
Sublease income	—	(220)
Total lease cost	$796	$1,334

	December 31, 2022	June 30, 2023
Other information:		
Weighted-average remaining lease term (in years)	1.9	1.4
Weighted-average discount rate	9.6%	11.6%

Cargo Therapeutics, Inc.
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Supplemental cash flow and noncash information related to the Company's operating leases were as follows:

(in thousands)	Six months ended June 30, 2022	2023
Cash flows from operating activities:		
Cash paid for amounts included in the measurement of lease liabilities	$684	$1,127
Right-of-use assets obtained in exchange for lease obligations:		
Total right-of-use assets capitalized	$ —	$2,291

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 occurred 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 can only be repaid prior to maturity upon consent of a majority of the investors or immediately upon demand.

The 2022 Convertible Notes are 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 are 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) may 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 may 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 have 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 will 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 do 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 year ended December 31, 2022 and the six months ended June 30, 2023, $1.2 million and $0.7 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 to June 30, 2023 (see Note 3). The aggregate fair value at issuance of the derivative liabilities was $13.6 million and is 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 is amortized using the effective interest rate method over the term of the respective note. For the six months ended June 30, 2022 and 2023, the Company recognized $0.8 million and $1.6 million, respectively, of interest expense, including accrued interest, amortization of the debt discount and amortization of debt issuance costs, in the statements 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 six months ended June 30, 2023.

7. Convertible preferred stock

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 is 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

Cargo Therapeutics, Inc.
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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 is 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 is obligated to sell 6,341,148 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.

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 (see Note 3).

Convertible preferred stock consisted of the following:

	December 31, 2022				
(in thousands, except shares and per share amounts)	**Shares authorized**	**Shares issued and outstanding**	**Original issue price**	**Liquidation preference**	**Carrying value**
Series Seed	11,000,000	810,700	$ 13.57	$ 11,000	$ 10,855
Total	11,000,000	810,700		$ 11,000	$ 10,855

Redeemable convertible preferred stock consisted of the following:

	June 30, 2023				
(in thousands, except shares and per share amounts)	**Shares authorized**	**Shares issued and outstanding**	**Original issue price**	**Liquidation preference**	**Carrying value**
Series Seed	11,000,000	810,700	$ 13.57	$ 11,000	$ 9,830
Series A-1	200,760,000	5,072,919	$ 13.57	$ 68,832	$ 60,760
Series A-2	43,824,255	3,229,851	$ 10.18	$ 32,868	$ 35,576
Total	255,584,255	9,113,470		$ 112,700	$ 106,166

The holders of redeemable convertible preferred stock have various rights, preferences and privileges as follows:

Voting rights

The holders of redeemable convertible preferred stock shares are entitled to vote on all matters on which the common stockholders are entitled to vote. Each holder of redeemable convertible preferred stock is entitled to

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the number of votes equal to the number of whole shares of common stock into which the shares held by such holder are convertible. Holders of the shares of Series A-1 redeemable convertible preferred stock, as a separate class, are entitled to elect two directors of the Company. Holders of the shares of Series Seed convertible preferred stock, as a separate class, are entitled to elect (i) prior to the issuance of the third tranche, two directors of the Company and (ii) on or after the issuance of the third tranche, one director of the Company. The holders of common stock are entitled to elect one director and one director will be the Company's Chief Executive Officer. The remaining two directors will be independent directors that are elected by stockholder vote and must be mutually acceptable to the other directors.

As long as at least 1,909,071 shares of redeemable convertible preferred stock shares remain outstanding, the Company must obtain approval from a majority of the holders of the then outstanding shares of redeemable convertible preferred stock, provided that prior to the issuance of third tranche such approval must include the affirmative vote of the holders of a majority of the outstanding shares of Series A-1 redeemable convertible preferred stock, to alter or change the rights, preferences and privileges of redeemable convertible preferred stock, change the authorized number of redeemable convertible preferred and common stock, create a new class or series of shares having any rights, preferences or privileges superior to or on parity with any outstanding shares of redeemable convertible preferred stock, declare or pay any distribution, merge, consolidate with or implement a reorganization that would result in the transfer of 50% of the voting power of the Company, sell all or substantially all of the Company's assets, voluntarily dissolve or liquidate the Company, change the authorized number of directors, incur indebtedness greater than $0.3 million and appoint or remove the chief executive officer.

Dividends

The Company's certificate of incorporation permits the holders of shares of redeemable convertible preferred stock to receive, only when, as and if declared by the Board of Directors, dividends at a rate of 8% of the applicable original issuance price of $13.57 per share for shares of Series Seed and Series A-1 redeemable convertible preferred stock and $10.18 per share for shares of Series A-2 redeemable convertible preferred stock, as adjusted for stock dividend, stock split, combination or other similar recapitalization (the "Original Issue Price"). Such dividend may be received prior and in preference to any declaration or payment of any other dividend (other than dividends on shares of common stock payable in common stock). Such dividends are non-cumulative. The Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company (other than dividends on shares of common stock payable in common stock) unless the holders of redeemable convertible preferred stock then outstanding shall first receive, or simultaneously received, in addition to the 8% dividend noted above, an equal dividend on an as converted basis, if the dividend is declared on common stock or securities convertible in common stock. If the dividend is declared on non-common stock or securities not convertible in common stock, the holders of redeemable convertible preferred stock then outstanding must also receive an equal dividend to the dividend of such class, divided by its issuance price and multiplied by the applicable Original Issue Price, provided that if the Company declares a dividend on the same date on shares on more than one class or series of stock the dividend payable to the redeemable convertible preferred stockholders shall be based on the dividend on the class or series that would result in the highest preferred dividend. No dividends were declared as of December 31, 2022 and June 30, 2023.

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Liquidation

In the event of any liquidation, dissolution 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 of consolidation, or the sale of substantially all of the assets 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, the holders of redeemable convertible preferred stock will receive in preference to any distribution of assets to the holders of common stock, an amount per share equal to the greater of (i) per share equal the Original Issue Price, plus any declared and unpaid dividends, or (ii) such amount as would have been payable had all shares of the redeemable convertible preferred stock been converted into common stock. If the assets available for distribution are insufficient then proceeds will be distributed ratably among the holders of redeemable convertible preferred stock in proportion to the full preferential amount that each such holder is entitled to receive. If there are remaining assets of the Company legally available for distribution after the payment of the full liquidation preference of the preferred stock, those remaining assets shall be distributed ratably to the holders of common stock based on the number of shares held by each common stockholder.

Conversion

Each share of redeemable convertible preferred stock is convertible, at the option of the holder, into the number of shares of common stock into which such shares are convertible at the then-effective conversion ratio. The conversion ratio is determined by dividing the applicable Original Issue Price by the then applicable conversion price. The initial conversion price per share is $13.57 for Series Seed preferred stock, $13.57 for Series A-1 preferred stock, and $10.18 for the Series A-2 preferred stock. The initial conversion price is subject to adjustment from time to time. Each share of redeemable convertible preferred stock shall automatically be converted into fully-paid, non-assessable shares of common stock at the then-effective conversion rate for such share (i) immediately prior to the closing of a firm commitment underwritten IPO pursuant to an effective registration statement filed under the Securities Act of 1933, as amended , resulting in at least $50.0 million of gross proceeds and in which the pre-money valuation of the Company is at least $400.0 million and in connection with such offering the common stock is listed for trading on the Nasdaq Stock Market's National Market or the New York Stock Exchange (ii) immediately prior to the consummation of a transaction by merger, consolidation, share exchange or otherwise in which the pre-money valuation of the Company is at least $400.0 million, with a publicly-traded special purpose acquisition company (a "SPAC"), immediately following the consummation of which the common stock or share capital of the SPAC or its successor entity is listed on the Nasdaq Stock Market or the New York Stock Exchange or another exchange approved by the Board of Directors, or (iii) at the date and time, or occurrence, of an event specified in a vote or written consent of the holders of the majority of the outstanding shares of redeemable convertible preferred stock.

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 of 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.

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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 7, 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.

The Company has elected not to adjust the carrying values of the redeemable convertible preferred stock to the redemption value of such shares, since it is not probable that a redemption event will occur. Subsequent adjustments to increase the carrying value to the redemption values will be made when it becomes probable that such redemption will occur.

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, subject to prior rights of the redeemable convertible preferred stockholders. In February 2023, the Company amended and restated its certificate of incorporation to increase the authorized shares of common stock to 320,000,000.

Common stock issued and outstanding on the balance sheets and statements of stockholders' 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, 2022	June 30, 2023
Redeemable convertible preferred stock	—	9,113,470
Convertible preferred stock	810,700	—
Common stock options issued and outstanding under the Plan	167,882	2,147,565
Remaining shares available for issuance under the Plan	22,928	502,192
Total reserved common stock	1,001,510	11,763,227

The 2022 Convertible Notes, which are excluded from the table above as of December 31, 2022, converted into shares of Series A-2 redeemable convertible preferred stock in February 2023 (see Notes 6 and 7).

9. Stock-based compensation

2021 Stock Option and Grant Plan

In July 2021, the Company established its 2021 Stock Option and Grant Plan (the "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 October 2022 and February 2023, the Board of Directors

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amended shares authorized for issuance under the Plan. As of December 31, 2022 and June 30, 2023, shares authorized for issuance under the Plan were 393,268 and 3,268,399, respectively.

Stock options

Stock option activity for the six months ended June 30, 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	1,985,027	$ 5.03		
Exercised	(1,695)	$ 1.09		
Cancelled and forfeited	(3,649)	$ 1.43		
Outstanding at June 30, 2023	2,147,565	$ 4.73	9.76	$ 641
Vested and expected to vest, June 30, 2023	2,147,565	$ 4.73	9.76	$ 641
Exercisable at June 30, 2023	53,479	$ 1.48	9.21	$ 190

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 June 30, 2023.

The aggregate intrinsic value of options exercised during the six months ended June 30, 2023 was $7,000. No options were exercised during the six months ended June 30, 2022. The estimated weighted-average grant-date fair value of options granted during the six months ended June 30, 2022 and 2023 was $0.79 and $3.71 per share, respectively. As of June 30, 2023, there was $6.9 million of unrecognized stock-based compensation related to stock options, which is expected to be recognized over a weighted-average period of 2.7 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 six 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.

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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	(9,384)	0.64
Vested	(148,914)	0.96
Unvested as of June 30, 2023	372,686	$ 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 $0.2 million and $0.1 million as a share repurchase liability for restricted stock awards in accrued expenses and other current liabilities on the balance sheets as of December 31, 2022 and June 30, 2023, respectively.

As of June 30, 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 of 2.6 years.

Stock-based compensation expense

Total stock-based compensation expense recorded in the statements of operations and comprehensive loss was as follows:

	Six months ended June 30,	
(in thousands)	**2022**	**2023**
General and administrative	$ 200	$ 427
Research and development	41	196
Total stock-based compensation expense	$ 241	$ 623

The estimated grant-date fair value of awards granted during the six months ended June 30, 2022 and 2023 was calculated based on the following assumptions:

	Six months ended June 30,	
	2022	**2023**
Expected term (in years)	3.6 – 6.1	5.7 – 6.3
Expected volatility	84.6% – 88.7%	85.5% – 86.8%
Expected dividend	—	—
Risk-free interest rate	0.6% – 3.2%	3.6%

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

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CAR T-cell therapies (the “Stanford License Agreement”). Pursuant to the Stanford License Agreement, 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.

As consideration for the licenses granted under the Stanford License Agreement, 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 Agreement 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 Agreement.

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 that achieves specific clinical trials or regulatory approvals, up to $0.6 million in milestone payments upon achievement of commercial milestone events and double-digit percentage milestone payments on non-patented products, and, subject to certain royalty reductions, low single-digit percentage royalties on net sales of products. Subject to the terms of the Stanford License Agreement, 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 Agreement, 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. No research and development expense related to the license was recognized during the six months ended June 30, 2023.

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The Company may be required to pay up to $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 Agreement”) with the U.S. Department of Health and Human Services, as represented by The National Cancer Institute (the “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-sublicenseable 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.

As consideration for the licenses granted under the 2022 NCI License Agreement, the Company is required to pay NCI a non-refundable license fee of $0.6 million, of which $0.2 million was paid in 2022, and the remaining balance of $0.4 million is payable in three equal annual installments beginning on the first 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 Agreement of which $0.3 million and $0.1 million are classified as other non-current liabilities on the balance sheet as of December 31, 2022 and as of June 30, 2023, respectively. The Company determined that the purchase of the license under the 2022 NCI License 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 initial consideration of $0.6 million under the 2022 NCI License Agreement as research and development expense in March 2022, upon entering into the 2022 NCI License Agreement. During the six months ended June 30, 2023, the Company recorded research and development expense of $0.1 million related to the minimum annual royalty and the achievement of the first clinical milestone.

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 at a low single-digit percentage, depending on the amount of annual net sales and subject to the terms of the 2022 NCI License Agreement. 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 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

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U.S. Food and Drug Administration ("FDA"). The Company is also obligated to pay NCI a percentage of the fair market value of the consideration the Company receives for any assignment of the 2022 NCI License Agreement to a non-affiliate (upon NCI's prior written consent) or an allocated portion of the fair value of consideration received in connection with a change in control.

NCI may terminate or modify the 2022 NCI License Agreement 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 NCI.

In February 2023, the Company entered into an exclusive license agreement (the "2023 NCI License Agreement") with NCI, pursuant to which the Company obtained a worldwide, royalty-bearing, exclusive license under certain patent rights owned by 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 both: receptors targeting CD19, CD20, and/or CD79b; and using STASH platform and/or a technology to activate CD2 signaling in the CAR T cell.

As consideration for the licenses granted under the 2023 NCI License Agreement, the Company must pay 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 NCI for $0.1 million in expenses incurred by 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 Agreement. The Company determined that the purchase of the license under the 2023 NCI License 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 initial consideration of $0.4 million under the 2023 NCI Agreement, consisting of the non-refundable upfront fees and patent expense reimbursement, as research and development expense in February 2023, upon entering the 2023 NCI License Agreement. The Company accrued these amounts upon entering into the 2023 NCI License Agreement of which $0.1 million is classified as other non-current liabilities on the balance sheet as of June 30, 2023.

The Company agreed to pay up to $0.1 million in regulatory milestone payments upon achieving 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 Agreement, 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 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 NCI a percentage of the fair market value of the consideration the Company receives for any assignment of the 2023 NCI License Agreement to a non-affiliate (upon NCI's prior written consent) or an allocated portion of the fair value of consideration received in connection with a change in control.

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Unless earlier terminated, the 2023 NCI License Agreement will expire upon the expiration of the last to expire licensed patent right. NCI may terminate or modify the 2023 NCI License Agreement 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 NCI.

11. Related parties

The 2022 Convertible Notes (see Note 6) 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 7).

Apart from the transactions and balances detailed in Note 6, Note 7 and Note 11, the Company has no other significant or material related party transactions during the six months ended June 30, 2022 and 2023.

12. 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:

	Six months ended June 30,	
(in thousands, except share and per share amounts)	**2022**	**2023**
Numerator:		
Net loss attributable to common stockholders	$ (14,917)	$ (30,599)
Denominator:		
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	298,296	634,704
Net loss per share attributable to common stockholders, basic and diluted	$ (50.01)	$ (48.21)

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):

	June 30, 2022	June 30, 2023
Redeemable convertible preferred stock, as converted	—	9,113,470
Convertible preferred stock, as converted	810,700	—
2022 Convertible Notes, as converted	1,191,800	—
Outstanding stock options	75,281	2,147,565
Restricted stock awards subject to repurchase	569,631	372,686
Total	2,647,412	11,633,721

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13. Subsequent events

Management has reviewed and evaluated material subsequent events from the balance sheet date of June 30, 2023 through September 1, 2023 the day the financial statements were available for issuance, and November 6, 2023 for the reverse stock split discussed below.

Series A redeemable convertible preferred stock financing

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 gross net proceeds of approximately $45.9 million.

Grant of stock options

In August 2023, the Company granted options for 1,078,806 shares of the Company's common stock to its employees, with an exercise price of $9.50 per share.

Amendment to the Plan

In July 2023, the Company amended the Plan to increase shares reserved and available for issuance under the Plan from 3,268,399 to 3,618,904 shares.

Reverse Stock Split

In November 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 convertible preferred stock on a 13.5685-for-1 basis (the "Reverse Stock Split"), which was effected on November 3, 2023. The authorized shares and the par value of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. Accordingly, all share data and per share data amounts for all periods presented in the financial statements and notes thereto have been retrospectively adjusted to reflect the effect of the Reverse Stock Split.

18,750,000 shares

Common stock

Prospectus

J.P. Morgan	**Jefferies**	**TD Cowen**	**Truist Securities**

November 9, 2023