UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

Commission File Number 001-41925

CG Oncology, Inc.

(Exact name of registrant as specified in its Charter)

Delaware	**37-1611499**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Spectrum Center Drive, Suite 2040 Irvine, CA	**92618**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (949) 409-3700

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	CGON	The Nasdaq Global Select Market

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

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

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

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

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

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

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

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

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

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

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

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

As of January 31, 2024, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $1.5 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $37.26 per share. The registrant has elected to use January 31, 2024 as the calculation date because, as on June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately held company.

As of March 25, 2024, the registrant had 66,636,252 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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FORWARD-LOOKING STATEMENTS AND MARKET DATA

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned clinical trials and preclinical studies for cretostimogene and any future product candidates, the timing and likelihood of regulatory filings and approvals for cretostimogene and any future product candidates, our ability to commercialize cretostimogene and any future product candidates, if approved, the pricing and reimbursement of cretostimogene and any future product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and potential to enter into any future strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated product development efforts, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This Annual Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Annual Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial and other trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions, including, without limitation, the risk factors described in Part I, Item 1A, “Risk Factors.” Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

In addition, statements that “we believe” and similarly qualified statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to rely unduly upon them.

This Annual Report includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ 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 trademarks and tradenames.

PART I

Item 1. Business.

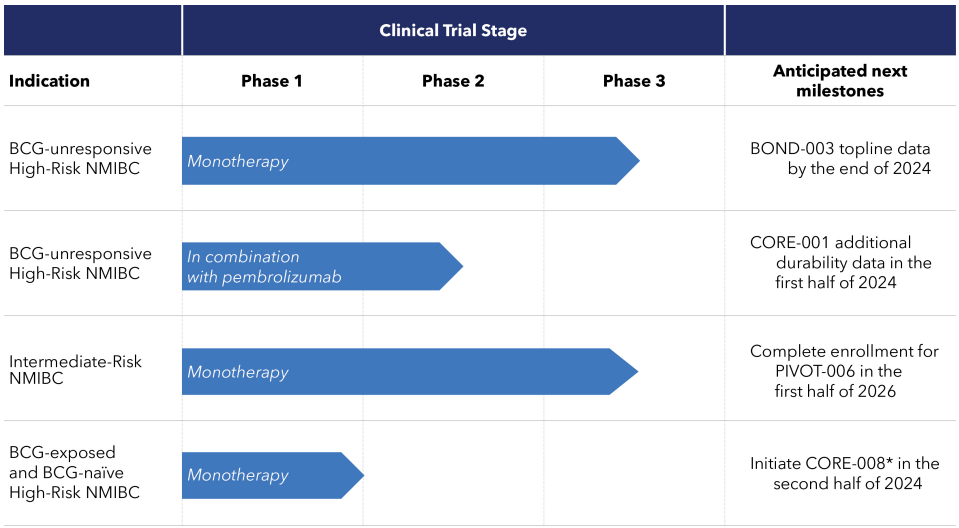
Overview

We are a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients afflicted with bladder cancer. Our product candidate, cretostimogene, is initially in clinical development for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to Bacillus Calmette Guerin (BCG) therapy, the current standard-of-care for high-risk NMIBC. There is significant unmet need for treatments in these patients given the limitations of currently approved therapies and patient reluctance to undergo radical cystectomy, or the complete removal of the bladder. We are evaluating the safety and efficacy of cretostimogene as monotherapy in BOND-003, our ongoing Phase 3 clinical trial in high-risk BCG-unresponsive NMIBC patients. We have completed enrollment for this trial, reported interim data in November 2023 and expect to report topline data by the end of 2024. If successful, we believe that this trial could serve as the basis for a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA). We are also evaluating the use of cretostimogene when administered to this same patient population in combination with FDA-approved pembrolizumab in CORE-001, our ongoing Phase 2 clinical trial. Moreover, we intend to assess the safety and efficacy of cretostimogene in treating a range of other bladder cancer indications as an alternative to BCG therapy and in patients who are not categorized as BCG-unresponsive, including our second Phase 3 clinical trial, PIVOT-006, evaluating adjuvant cretostimogene in intermediate-risk NMIBC patients following transurethral resection of the bladder tumor (TURBT). We believe cretostimogene, if approved, has the potential to serve as first-line therapy, thereby alleviating the current need to prioritize treatment recipients and ration administration of BCG given its significant market shortage.

Cretostimogene has shown clinical benefit and has been generally well-tolerated as both a monotherapy and in combination with other therapies in clinical trials to date. Interim data for BOND-003 was reported at the 24th Annual Meeting of Society of Urologic Oncology (SUO) on November 30, 2023. As of the October 5, 2023 efficacy data cutoff, 50 of the 66 (75.7%; 95% CI: 63-85%) evaluable patients achieved a complete response (CR), generally meaning no evidence of bladder cancer, at any time after the administration of cretostimogene. In addition, as of the data cutoff, 45 out of 66 (68.2%) patients achieved a CR at three months and 42 out of 66 (63.6%) patients achieved a CR at six months. Four out of 13 (30.8%) patients who did not achieve a CR at three months, and who were subsequently re-dosed with cretostimogene at three months demonstrated a CR at six months. Of those 50 patients who achieved a CR at any time, 42 out of 50 (84.0%) maintained their response for at least three months and 32 out of 43 (74.4%) maintained their response for at least six months. Seven patients had yet to reach the minimum duration of response (DOR) evaluation and were excluded from the assessment for durable CR lasting at least six months. A DOR is the length of time from the first response until the time the patient no longer meets the definition for a CR. Cretostimogene was generally well-tolerated in this trial as of the September 8, 2023 safety data cutoff, with mostly Grade 1 or Grade 2 adverse events reported and no Grade 3 or higher treatment-related adverse events (TRAEs) reported. There were no treatment discontinuations due to TRAEs and no deaths were reported. Two patients (1.8%) had serious adverse events (SAEs) including Grade 2 noninfective cystitis, which is the inflammation of the bladder not caused by a bacteria or other infectious agent, and Grade 2 clot retention, both of which resolved. In addition, in our ongoing open-label Phase 2 CORE-001 clinical trial of cretostimogene in combination with pembrolizumab in high-risk BCG-unresponsive NMIBC, 29 of the 34 (85%; 95% CI: 68-94%) patients evaluable as of the March 3, 2023 data cutoff achieved a CR after an initial induction course of therapy, with 82% (n=27/33) of patients maintaining a CR at six months, and 68% (n=17/25) of patients maintaining a CR at 12 months. Cretostimogene was generally well-tolerated in this trial as of the January 31, 2023 safety data cutoff, with one Grade 2 SAE (urinary retention) deemed related to cretostimogene and two Grade 3 serious SAEs related to pembrolizumab (adrenal insufficiency and immune-mediated hepatitis), all of which resolved. Cretostimogene has received fast track designation from the FDA for the treatment of BCG-unresponsive, high risk NMIBC patients with carcinoma in-situ with or without Ta or T1 papillary tumors to improve CR. We have presented the confidence interval (CI) for CR at any time above and elsewhere in this Annual Report. CI is a range of values in which, statistically, there is a specified level of confidence where the result lies. It is conventional to set the CI at 95%, which means 95 of 100 times, the CI will contain the true value. The lower bound of the 95% CI around the observed CR rate provides support that such rate may be clinically meaningful. Interim results from these trials may differ from future results of the trials as more patient data become

available. We intend to evaluate cretostimogene for use in a variety of bladder cancer treatment settings, as shown in our pipeline below.

Our Cretostimogene Pipeline



* Planned clinical trial to be conducted under existing Investigational New Drug application (IND) previously cleared by the FDA.

Our Strengths

We believe our product candidate is differentiated by several strengths that support our vision of cretostimogene as a potential backbone therapy in bladder cancer, including:

- Demonstrated monotherapy clinical utility and durability of response, with a 75.7% (95% CI: 63-85%) CR at any time, in addition to 74.4% of evaluable responders maintaining their response for at least six months as of October 5, 2023 in our ongoing Phase 3 BOND-003 cretostimogene monotherapy trial.
- Observed tolerability, with no Grade 3 or higher TRAEs or patient discontinuations due to TRAEs as of September 8, 2023 in our ongoing Phase 3 BOND-003 cretostimogene monotherapy trial.
- Cretostimogene is administered intravesically and uses a similar route of administration as standard-of-care BCG therapy which urology practices perform regularly. This is unlike some treatment procedures that require a urologist to perform a cystoscopic examination that involves local anesthesia.
- The potential for deploying cretostimogene in combination with other therapies due to its observed tolerability and novel mechanism of action, supported by 85% (95% CI: 68-94%) of patients having shown a CR at any time in our ongoing Phase 2 CORE-001 clinical trial of cretostimogene in combination with the checkpoint inhibitor (CPI) pembrolizumab as of March 3, 2023.
- Cretostimogene's potential broad applicability across bladder cancer indications, beginning with high-risk BCG-unresponsive NMIBC, and expanding into intermediate-risk and BCG-exposed and BCG-naïve high-risk NMIBC, with potential incremental opportunity in muscle invasive bladder cancer (MIBC).

Bladder Cancer Overview

Bladder cancer is a heterogeneous disease and involves a number of different cancer sub-types, which can be segmented into NMIBC or MIBC. The American Cancer Society estimates that in 2024, more than 82,000 people will be diagnosed with bladder cancer and that the disease will result in nearly 17,000 deaths. An estimated 725,000 people in the United States are currently living with the disease. NMIBC, which accounts for approximately 75% of newly

diagnosed patients, describes earlier-stage bladder cancer that has not spread to the muscle wall. NMIBC can be further stratified by its specific risk profile, with high-risk NMIBC patients, who make up approximately 40% of the NMIBC patient population, at an elevated probability of disease progression to more aggressive MIBC within five years of initial diagnosis. Patients with intermediate-risk disease account for approximately 30% of total NMIBC diagnoses.

Current treatment for high-risk NMIBC typically involves TURBT followed by the intravesical (IVE) delivery of BCG therapy to induce a non-specific anti-tumor immune response. This treatment protocol has demonstrated therapeutic benefit with nearly 70% of patients achieving a CR following an initial induction course of therapy. However, approximately 50% of these patients will experience a recurrence of the tumor and few treatment options are available for patients who become unresponsive to BCG treatment. While radical cystectomy is the current standard-of-care for BCG-unresponsive patients, only approximately 6% of NMIBC patients elect to undergo the procedure in light of the significant social, functional and emotional burden associated with it. Further complicating the treatment options available to NMIBC patients is the ongoing shortage of BCG which has restricted patient eligibility to high-risk BCG-naïve patients only. Even among these patients a significant number of newly-diagnosed, BCG-eligible, treatment-naïve patients in the United States may not receive sufficient BCG therapy, if at all. Moreover, patients with intermediate-risk NMIBC may not have access to BCG due to the shortage, despite the likely therapeutic benefit of earlier adjuvant BCG therapy, because high-risk patients are prioritized in line with guidance published by the National Comprehensive Care Network (NCCN) and guidance published jointly by the American Urological Association (AUA) and the SUO.

Instances of refractory and recurrence disease, patient aversion to cystectomy and the ongoing BCG supply constraints, have created a sizeable unmet medical need for alternative NMIBC therapeutics that are both safe and efficacious. Beyond our ongoing clinical trials in NMIBC, we also intend to initiate CORE-008, an open-label multi-cohort Phase 2 clinical trial designed to assess the safety and efficacy of cretostimogene when administered as monotherapy in high-risk NMIBC patients including BCG-exposed and BCG-naïve NMIBC patients. BCG-exposed patients are classified as those NMIBC patients with persistent, recurrent or progressive disease after BCG treatment but who do not meet the specific disease classification criteria requisite to be designated as BCG-unresponsive. BCG-naïve patients are classified as those NMIBC patients who have not received any prior BCG therapy.

In addition to NMIBC, we are also evaluating cretostimogene as a potential therapeutic to treat patients with MIBC. MIBC is a more aggressive form of bladder cancer than NMIBC and is associated with significantly higher mortality. In CORE-002, an ongoing single-arm exploratory investigator-sponsored clinical trial, cretostimogene is being evaluated in combination with the CPI nivolumab in MIBC patients ineligible for cisplatin chemotherapy prior to radical cystectomy.

Our Strategy

We intend to become a leading company in the development and commercialization of innovative therapeutics to treat cancer, with an initial focus on bladder cancer. Key elements of our strategy to accomplish this objective include:

- **Complete the ongoing BOND-003 Phase 3 trial of cretostimogene as monotherapy in high-risk BCG-unresponsive NMIBC and pursue FDA approval.** We are evaluating the safety and efficacy of cretostimogene in BOND-003, our ongoing Phase 3 clinical trial. We have completed enrollment for this trial, reported interim data in November 2023 and expect to report topline data by the end of 2024. Given the significant unmet need in this indication, the FDA published guidance in 2018 that stated a single-arm clinical trial in patients with BCG-unresponsive NMIBC that assess CR rate as the primary endpoint, taking DOR into account, may be appropriate for full approval. Based on this guidance, we believe that, if successful, our BOND-003 trial could serve as the basis for a BLA submission to the FDA.
- **Expand the development of cretostimogene monotherapy as a potential backbone therapy across NMIBC indications**. In addition to evaluating cretostimogene in patients with high-risk BCG-unresponsive NMIBC, and in light of the significant and ongoing global shortage of BCG, we intend to evaluate the safety and efficacy of cretostimogene as an alternative to BCG therapy in additional bladder cancer indications, including: (1) patients diagnosed with intermediate-risk NMIBC, who would likely benefit from earlier therapeutic intervention but are currently lacking access to BCG therapy, in our

PIVOT-006 Phase 3 clinical trial; and (2) patients with high-risk BCG-exposed and BCG-naïve NMIBC in our planned CORE-008 open-label multi-cohort Phase 2 clinical trial. Through expanding the clinical evaluation of cretostimogene across NMIBC indications, we will attempt to address the significant unmet need in treatment of bladder cancer, with over 82,000 new U.S. diagnoses per year and over 725,000 patients living with bladder cancer in the United States, according to the American Cancer Society. We believe cretostimogene, if approved, has the potential to serve as first-line therapy, thereby alleviating the current need to prioritize treatment recipients and ration administration of BCG given its significant market shortage.

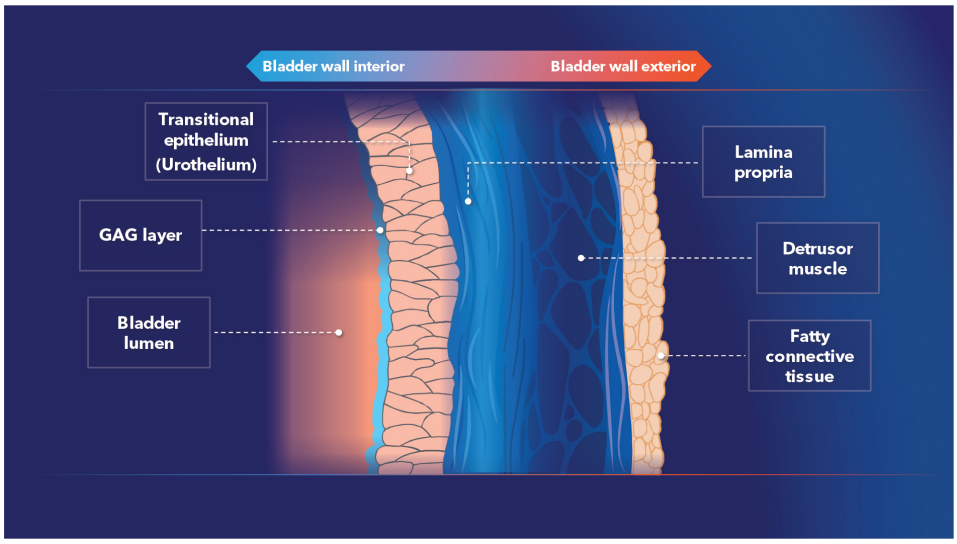
- **Continue to evaluate cretostimogene in combination with other therapies, such as CPIs, to potentially further enhance its clinical utility across various stages of bladder cancer.** As of December 31, 2023, cretostimogene had been administered in over 270 patients with a broad range of NMIBC risk profiles across multiple clinical trials and has been generally well-tolerated with no Grade 4 or 5 TRAEs observed and no treatment-related study discontinuations deemed related to cretostimogene. Based on observed tolerability data to date, we plan to evaluate the safety and efficacy of cretostimogene in combination with other therapies in addition to our monotherapy trials. These include our ongoing Phase 2 CORE-001 trial in combination with pembrolizumab for BCG-unresponsive NMIBC, and CORE-002, an ongoing exploratory investigator-sponsored single arm clinical trial in combination with nivolumab in MIBC. We believe our approach to combine cretostimogene with other therapeutics across several bladder cancer indications may potentially enhance the potential utility of our product candidate beyond our core strategy of targeting intermediate- and high-risk NMIBC via cretostimogene monotherapy.
- **Build our operational capabilities to successfully commercialize cretostimogene**. If we obtain FDA regulatory approval for cretostimogene, we intend to build in-house sales and marketing capabilities to commercialize cretostimogene in the United States. While the number of patients suffering from bladder cancer is large and growing, a high volume of patients is concentrated in a small number of high value targets and a significant portion of large urology practices including academic urology practices that are concentrated in a relatively small number of major metropolitan areas. We believe this concentration will potentially enable us to efficiently reach a large portion of our addressable market with a relatively small commercial footprint. Importantly, urology practices are already deeply familiar with IVE delivery of BCG in NMIBC patients. Cretostimogene is similarly administered via IVE in the clinic setting by a nurse or medical assistant, and therefore does not require urologists nor anesthesia. We believe this could drive increased physician adoption and improve patient experience versus alternative treatments that require urology practices to learn an entirely new and unfamiliar procedure or to transfer them to a medical oncologist for treatment and follow-up.
- **Leverage our CMC expertise and relationships to scale commercialization efforts**. We have established in-house CMC expertise made up of individuals with oncolytic immunotherapy manufacturing experience, enhanced by an advisory board to help oversee our overall CMC strategic focus, while leveraging third parties for product manufacturing. We believe this approach will drive a high-yield manufacturing process capable of rapidly scaling to meet demand should cretostimogene receive FDA approval. We have established a world class CMC Advisory Board providing differentiated expertise in production and potential commercialization of cretostimogene. Our CMC Advisory Board represents former senior leadership from large pharmaceutical companies with deep experience in manufacturing at scale, as well as former FDA leadership. We believe our strategic CMC approach will potentially enable us to maintain an attractive cost of goods while rapidly achieving commercial scalability, if cretostimogene receives FDA approval.

Bladder Cancer

The human bladder, which functions in the storage and elimination of urine, is a hollow muscular organ composed of multiple tissue layers. As shown below, the inner wall of the bladder is the urothelium, or transitional epithelium. The interior space where urine collects is known as the bladder lumen. The internal side of the urothelium is lined by a glycosaminoglycan (GAG) membrane, which acts as a protective barrier from urine as well as infectious agents. Between the thick, detrusor muscular portion of the bladder wall and the urothelium is the lamina propria,

which consists of connective tissue, blood vessels and nerves. A fatty connective tissue layer makes up the organ's exterior surface, facing the rest of the body.

The Anatomy of the Bladder Wall



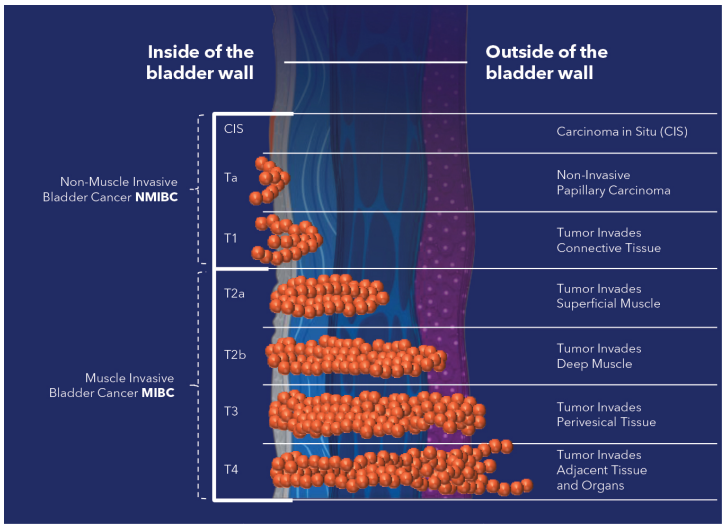
The American Cancer Society estimates that in 2024, more than 82,000 people will be diagnosed with bladder cancer in the United States and that it will result in nearly 17,000 deaths. Notable is the disease prevalence with an estimated 725,000 people in the United States living with the disease. The relatively high prevalence rate is driven in part by chances of recurrence, which can be very high for NMIBC. It is estimated that approximately 15% to 61% of high-risk patients with NMIBC will develop recurrence within one year following treatment and approximately 31% to 78% of people with NMIBC will develop recurrence or a secondary bladder cancer within five years following treatment, depending on risk-factors. Bladder cancer is the sixth most common form of cancer in the United States, and men account for three-quarters of newly diagnosed cases. Bladder cancer patients are generally from high-risk populations, with 74% of patients over 65 years old and a median age of 73 years old. The global bladder cancer treatment market has been forecast to be approximately $9.9 billion by 2028, according to Evaluate Pharma.

Bladder cancer is a heterogeneous disease and involves a number of different cancer sub-types. In the United States, the vast majority of patients with bladder cancer, accounting for approximately 90% of all diagnoses, have urothelial carcinoma (UC). UC is further segmented into two subtypes, papillary and non-papillary. Papillary UC involves tumors configured as finger-like projections extending from the transitional epithelium into the bladder lumen. Non-papillary, or flat, UC, also known as carcinoma *in situ* (CIS), which means the cancer is confined to the transitional epithelium, is generally difficult to treat via resection. The 5% of bladder cancer that is not UC includes squamous cell carcinomas, adenocarcinomas, sarcomas and small cell carcinomas.

NMIBC is often used to describe earlier stage disease that has not reached the muscle wall. NMIBC accounts for approximately 75% of newly diagnosed patients, and includes three stages: CIS-containing tumors, Ta and T1. Ta and T1 are papillary UCs which have not spread beyond the lamina propria. T2 through T4 stage make up MIBC, indicative of more aggressive locally advanced and metastatic disease. Bladder cancer has metastasized in an estimated

5% of patients with newly diagnosed disease. The graphic presented below illustrates the differences in disease progression represented by these stages.

Bladder Cancer is Classified as either NMIBC or MIBC.



NMIBC may be further differentiated by the risk of progression to MIBC. NMIBC patients with high-grade Ta or T1 stage cancer, any cancer containing CIS (which can occur in any grade of NMIBC or MIBC), and large volume or recurrent Ta stage tumors are considered to be high-risk tumors. Approximately 40% of patients with NMIBC have high-risk disease. Intermediate-risk NMIBC includes mostly low-grade Ta tumors that recur within 12 months, solitary low-grade Ta tumors greater than three centimeters, multifocal low-grade Ta tumors, or high-grade Ta tumors less than or equal to three centimeters. Intermediate-risk NMIBC accounts for an estimated 30% of patients with NMIBC. Low-risk NMIBC consists of low-grade solitary Ta stage tumors and makes up the remaining 30% of NMIBC cases.

Current Treatment for NMIBC and its Limitations

Regardless of risk stratification, treatment of NMIBC generally involves TURBT, a surgical procedure involving an instrument inserted through the urethra enabling the visual inspection and biopsy of the lesion along with removal of the cancerous cells allowing a patient with NMIBC to retain normal bladder function. Use of TURBT alone is associated with a five-year estimated recurrence rate of approximately 44% to 63%, and remains a backbone of early NMIBC treatment regimen. CIS-containing tumors cannot be resected using TURBT. Progression to a more advanced stage or grade subsequent to initial diagnosis is also commonly encountered. As such, in both high-risk and intermediate-risk NMIBC patients, surgical removal of NMIBC tumors through TURBT is often accompanied by the delivery of adjuvant BCG therapy or chemotherapy, through IVE delivery.

BCG therapy involves the use of a live, attenuated mycobacterium to induce a non-specific anti-tumor immune response in the bladder mucosa and provides meaningful therapeutic utility in the treatment of NMIBC. The use of BCG therapy following TURBT has exhibited sustained anti-tumor activity, with nearly 70% of patients experiencing a CR after an initial induction course of therapy. Despite BCG's effectiveness, there is a significant global shortage of BCG as described below. In addition, approximately 50% of these patients will experience a recurrence of the tumor and few treatment options are available for patients who become unresponsive to BCG treatment.

Patient Classification

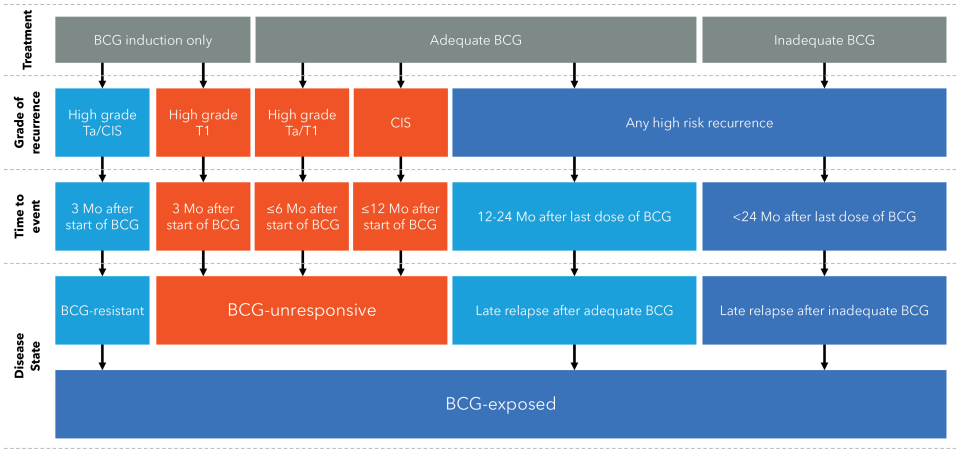
NMIBC is a heterogeneous disease with significant variation in individual risk of recurrence and progression to MIBC. In clinical practice, patients fall on a spectrum of high-risk NMIBC extending from BCG-naïve NMIBC, which

refers to patients who haven't received BCG treatment, at one end to BCG-unresponsive NMIBC at the other. Numerous iterations of guidelines on disease classification have evolved over time, primarily from medical industry groups such as the AUA. In February 2018, the FDA published guidance titled "BCG-Unresponsive Non muscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment," in order to assist sponsors in the development of drugs, including biologics, for the treatment of BCG-unresponsive NMIBC patients. The FDA guidance provides disease-state definitions and advice on patient selection, risk stratification, and clinical trial design in the BCG-unresponsive NMIBC patient population.

According to the 2018 FDA guidance, BCG-unresponsive NMIBC is defined as being at least one of the following: (1) persistent or recurrent CIS alone or with recurrent Ta/T1 disease within 12 months of completion of adequate BCG therapy; (2) recurrent high-grade Ta/T1 disease within six months of completion of adequate BCG therapy; or (3) T1 high-grade disease at the first evaluation following an induction BCG course.

In this context, adequate BCG therapy is defined as at least one of the following: (1) at least five of six doses of an initial induction course plus at least two of three doses of maintenance therapy, or (2) at least five of six doses of an initial induction course plus at least two of six doses of a second induction course.

In between BCG-naïve and BCG-unresponsive NMIBC lies a disease state where patients do not meet the criteria for either definition called BCG-exposed, which describes a combination of disease states related to prior BCG treatment that are neither BCG-naïve nor BCG-unresponsive. The chart below shows the various treatment pathways leading patients to be classified as BCG-unresponsive or BCG-exposed.



Patients will be classified as BCG-exposed in many cases including: (1) persistent or recurrent high-grade Ta or CIS-containing disease within three months of completion of an induction course of BCG therapy; (2) any high-risk recurrence after completion of adequate BCG therapy outside of the BCG-unresponsive window; or (3) any high-risk recurrence after completion of inadequate BCG therapy within a 24-month window.

According to AUA risk stratification guidelines, intermediate-risk NMIBC is defined as at least one of the following:

- Low-grade urothelial carcinoma
  - Low-grade T1 disease
  - Solitary low-grade Ta disease > 3 cm
  - Multifocal low-grade Ta disease
  - Recurrent low-grade Ta disease within 1 year

- High-grade urothelial carcinoma
    - Solitary High-grade Ta ≤ 3cm

Limited Treatment Options for High-risk BCG-unresponsive NMIBC Patients

While BCG has been the standard adjuvant therapy for high-risk NMIBC after TURBT, BCG is not without its limitations; it is estimated that approximately 50% of patients eventually develop tumor recurrence. While a subset of these patients will respond to a second round of BCG induction therapy, few treatment options are available to those who are BCG-unresponsive. IVE-delivery of chemotherapy has demonstrated limited benefit. The CR rate reported for valrubicin, the only approved chemotherapy for BCG-refractory patients, is 18% at six months. CIS-containing tumors are typically not considered resectable, further limiting treatment options for BCG-unresponsive patients. Failure to achieve a CR is associated with an increased risk of death or a disease-worsening event. As such, the use of valrubicin in this setting has not been widely adopted.

In January 2020, pembrolizumab, sold by Merck, was approved by the FDA to treat high-risk BCG-unresponsive NMIBC as monotherapy based on the results of the KEYNOTE-057 Phase 2 clinical trial. In the cohort of participants with CIS-stage tumors, with or without papillary tumors, 39 of 96 patients, or 41%, had a CR at 3 months, with the median duration of response being 16.2 months. The percentage of trial participants with a CR declined to 19% at 12 months. Among the trial cohort involving BCG-unresponsive, high-risk non-CIS papillary tumors the 12-month disease free survival (DFS) rate was 43.5% with a median DFS of 7.7 months. Patients in KEYNOTE-057 were administered systemic pembrolizumab by a medical oncologist by infusion every 3 weeks for up to 24 months or until disease persistence, recurrence, progression, unacceptable toxic effects, or withdrawal of consent. Across both trial cohorts, Grade 3 or 4 toxicities were observed in 13% of participants, of which the most common were hyponatremia and arthralgia. Serious treatment-related adverse events were noted in 8% of patients, including but not limited to colitis, autoimmune nephritis, hyperthyroidism, lymphocyte count decrease, pulmonary embolism, and syncope. Seven percent of patients discontinued due to TRAEs (cholestatic hepatitis, hyponatremia, nephritis, and type 1 diabetes mellitus).

Nadofaragene firadenovec (nadofaragene), a non-replicating adenoviral-based gene therapy produced by Ferring that activates interferon a2b, was approved by the FDA in December 2022 to treat high-risk BCG-unresponsive NMIBC CIS-stage, with or without papillary tumors. In a Phase 3 clinical trial evaluating nadofaragene for the treatment BCG-unresponsive NMIBC, 51% of patients achieved a CR and 24% of patients maintained a CR at 12 months. Grade 3 or 4 treatment-related adverse events occurred in 4% of patients, including micturition urgency, bladder spasms, urinary incontinence, syncope, and hypertension. Serious treatment-related adverse events were reported in 2% of patients (syncope, sepsis, and hematuria).

Based in part on a retrospective analysis of high-risk NMIBC patients, combination chemotherapy of gemcitabine and docetaxel are used in practice, although these drugs have not received FDA approval for this indication.

Given the significant unmet medical need, several additional potential treatments for NMIBC are in various stages of clinical development and regulatory approval. There are multiple companies that have reported drug candidates in clinical development. For example, ImmunityBio Inc.'s N-803 is an IVE-delivered IL-15 agonist delivered in combination with BCG. N-803's regulatory application received a complete response letter from the FDA due to deficiencies in pre-license inspections of the company's third-party manufacturers. In addition, Urogen Pharma, Inc.'s UGN-102 is an IVE-delivered DNA synthesis inhibitor, mitomycin, in gel formulation for treatment of low-grade intermediate-risk BCG-naïve NMIBC. Janssen Pharmaceuticals, Inc.'s TAR-200 is a drug delivery system administered via cystoscopic procedure every three weeks for the first 24 weeks (administered by a urologist in a procedure room under local anesthesia) with a continuous controlled-release dose of gemcitabine for treatment of BCG-unresponsive NMIBC. enGene, Inc.'s EG-70 is an IVE-delivered IL-2 and RIG-I dual-agonist.

Patient Aversion to Complete Removal of the Bladder as well as Underlying Mortality Risk

Radical cystectomy, or the complete removal of the bladder, remains the standard of care for high-risk BCG-unresponsive NMIBC patients, but commonly requires an ostomy appliance for urinary diversion. Despite being the

standard of care, only approximately 6% of high-risk BCG-unresponsive NMIBC patients elect to have a radical cystectomy. This hesitancy is associated with significant social, functional and emotional burden. Cystectomy and the radical change in daily routine required often results in diminished body image perception. While the physical and functional trauma may subside, the psychological and emotional burden associated with the consequences of the surgery, which may extend to a patient's caregivers and healthcare providers, remain. In addition, the procedure is associated with high degrees of morbidity and mortality. Approximately 64% of patients undergoing a radical cystectomy experience complications, with approximately 26% of patients requiring readmission for surgery-related complications and an overall readmission rate estimated to be between 20% and 29%. Moreover, the mortality rate within 90 days of the procedure is between 2% and 5%, likely associated with the more advanced age of many bladder cancer patients.

The Chronic Short Supply of BCG is Expected to Persist for Years

A key current issue with BCG is that continual production shortages have left many urological practices in need of an effective and readily available alternative first-line treatment. The production of BCG therapy involves a lengthy and complex manufacturing process and is produced for both the United States and most international markets by a single manufacturer, Merck. In 2017, Sanofi discontinued production of Connaught BCG after a history in challenges producing the product, including a shutdown following a 2011 FDA inspection of documented nonconformances including isolation of mold within the BCG aseptic processing areas, which further exacerbated the overall availability of BCG in the United States. While there are other options globally for BCG, none of the options are available in the United States, except for the TICE BCG strain manufactured by Merck. A randomized controlled, head-to-head trial may be needed to fully examine the impact of different BCG strains on clinical outcomes for bladder cancer patients.

BCG has been in short supply for over ten years as demand has outpaced available production capacity. In light of these supply constraints, the use of BCG therapy as induction therapy has been restricted to BCG-naïve, high-grade T1 or CIS-containing NMIBC patients only, with maintenance therapy limited to 12 months. The NCCN and AUC/SOC guidelines no longer recommend BCG therapy for intermediate-risk NMIBC, instead indicating that BCG should be prioritized for high-risk NMIBC patients only. Moreover, even among BCG-eligible patients, drug shortages have in some cases necessitated a reduction from a full-dose course of treatment.

In October 2020, Merck announced plans to build an additional BCG manufacturing site and has stated that construction is underway, and the new facility is on track to be completed between late 2025 and late 2026. The current market is only producing 69% of the estimated BCG need based on 2018 baseline volume; even with additional supply, the annual supply gap could be significant. We believe that disease recurrence after BCG therapy, together with current and anticipated ongoing supply shortages, highlights a significant unmet medical need for alternative NMIBC therapeutics which are both safe and efficacious, particularly in the intermediate- and high-risk NMIBC patient populations for whom BCG therapy is not available.

Significant Barriers Exist in Development and Adoption of New Treatments for NMIBC

Treatments that require administrative methods differing from BCG, such as requirements for operating/procedure room time under anesthesia or intravenous (IV) administration, may limit physician adoption, particularly in community urology practices. Further, we believe any treatment seeking to replace or compete with TURBT in intermediate-risk NMIBC will face slow adoption given TURBT's place as a cornerstone treatment for urology practices, driving a significant portion of providers' economics. In addition, treatments leveraging chemotherapies have demonstrated tolerability challenges and adverse events that limit their potential to be combined with other therapeutic agents to further enhance the efficacy profile. Cretostimogene's administration, which is similar to BCG, could offer convenience for urology practice adoption that will potentially allow cretostimogene to become a backbone therapy across several bladder cancer indications, if successfully developed and approved.

Cretostimogene: Our Product Candidate for Intermediate- and High-Risk NMIBC

Cretostimogene is an investigational engineered oncolytic immunotherapy that has been designed both to eliminate cancer cells directly by selective replication within cancer cells and indirectly activating an anti-tumor immune response. Our ongoing open-label Phase 3 clinical trial, BOND-003, is designed to assess the safety and efficacy of cretostimogene in high-risk BCG-unresponsive NMIBC when administered as a monotherapy. We have

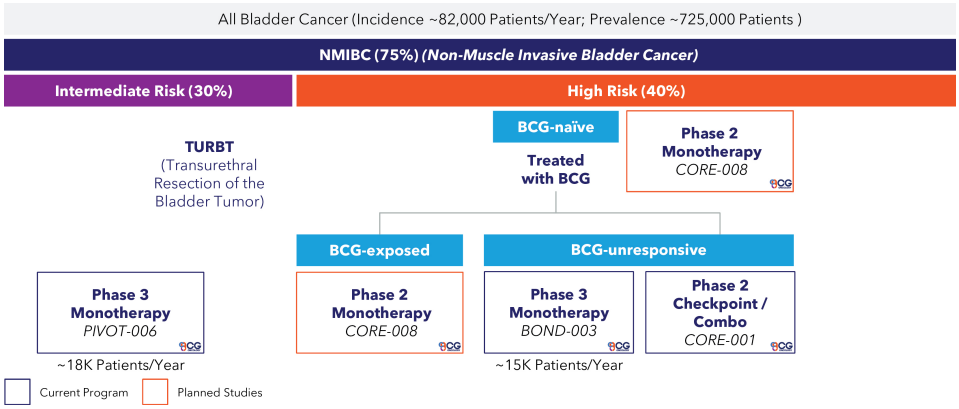
completed patient enrollment in the 115-patient BOND-003 trial and expect to report topline data by the end of 2024. We are also evaluating the safety and efficacy of cretostimogene when used in combination with pembrolizumab in CORE-001, our open-label Phase 2 clinical trial in this same patient population. We believe the clinical trial results observed to date reflect the differentiated therapeutic potential of cretostimogene.

Cretostimogene has shown clinical benefit and has been generally well-tolerated as both a monotherapy and in combination in clinical trials to date. In BOND-003, 50 of the 66 (75.7%; 95% CI: 63-85%) of the evaluable patients achieved a CR at any time after the administration of cretostimogene as of the October 5, 2023 efficacy data cutoff. Of those 50 responders, 42 out of 50 (84.0%) maintained their response for at least three months and 31 out of 43 (74.4%) maintained their response for at least six months as of the data cutoff. Cretostimogene has also demonstrated clinical activity when administered in combination with pembrolizumab to patients with high risk, BCG-unresponsive NMIBC in our ongoing Phase 2 CORE-001 open-label clinical trial. In this trial, 29 of the 34 (85%; 95% CI: 63-85%) patients evaluable as of the March 3, 2023 data cutoff achieved a CR after an initial induction therapy, with 82% (n=27/33) of evaluable patients maintaining a CR at six months, and 68% (n=17/25) of evaluable patients maintaining a CR at 12 months. As of December 31, 2023, cretostimogene has been administered in over 270 patients during clinical trial investigations, and has been generally well-tolerated with no Grade 4 or 5 TRAEs observed and no treatment-related study discontinuations deemed related to cretostimogene. There have been no discontinuations from CORE-001 related to cretostimogene.

We initiated PIVOT-006 in November 2023, which is a randomized Phase 3 clinical trial designed to assess the safety and efficacy of adjuvant cretostimogene in intermediate-risk NMIBC patients following TURBT. We also intend to initiate CORE-008, which is an open-label multi-cohort Phase 2 clinical trial designed to assess the safety and efficacy of cretostimogene when administered as monotherapy, including in (1) high-risk NMIBC patients categorized as BCG-exposed but not yet designated unresponsive, and (2) high-risk NMIBC patients categorized as BCG-naïve.

Our ongoing and planned clinical trials and the specific NMIBC patient population to be evaluated are presented in the following chart.

Clinical Trials are Ongoing or Planned to Evaluate Cretostimogene in a Range of NMIBC Patient Populations



We believe NMIBC patients with BCG-unresponsive disease are unlikely to benefit from further BCG therapy. Additionally, given the patient burden and mortality associated with cystectomy, bladder preservation through the avoidance or delay of cystectomy is an intended outcome of new therapeutic product candidates for bladder cancer. We believe our approach is supported by the February 2018 FDA guidance regarding clinical trial design targeting a BCG-unresponsive, CIS-containing NMIBC patients states that a single-arm trial that assesses CR rate as the primary endpoint, taking DOR into account, may be appropriate for full approval, or may require a confirmatory trial after

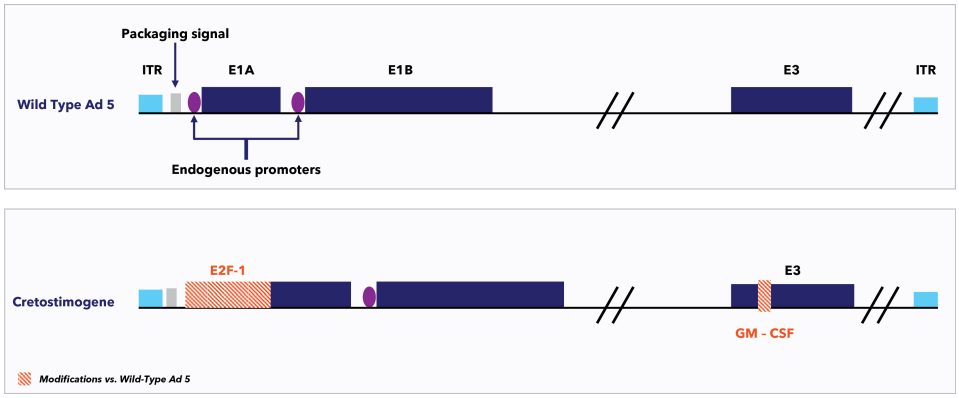
accelerated approval. As of December 31, 2023, there were two products that have received full FDA approval based on data from single-arm clinical trials following the issuance of the guidance.

Cretostimogene Grenadenorepvec

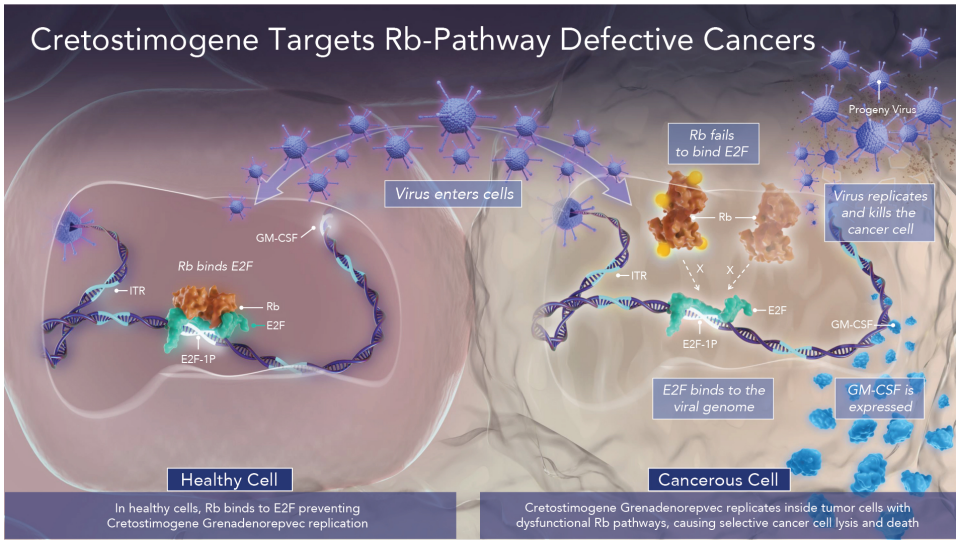
Cretostimogene is an investigational engineered, conditionally replicating oncolytic immunotherapy that has been designed to preferentially replicate in retinoblastoma (Rb) gene pathway-defective cells present in the majority of urothelial carcinomas and trigger an anti-tumor immune response. Cretostimogene enters the tumor by binding to Coxsackievirus and Adenovirus Receptors (CAR) present in specialized intracellular junctions and tight junctions of polarized epithelial cells.

There are two modifications made to cretostimogene for tumor selectivity and potency. The first modification is the insertion of an E2F-1 promoter in cretostimogene which acts as a safety mechanism to selectively replicate and lyse Rb-defective tumor cells rather than healthy cells which have intact Rb pathways. The second modification is the insertion of the gene for the cytokine granulocyte-macrophage colony stimulation factor (GM-CSF). GM-CSF is widely recognized as a potent stimulator of longer-term anti-tumor activity and we believe its addition to the viral construct may both prime the immune system and induce tumor-specific immunity. Replication and lysis of Rb-defective tumor cells by cretostimogene may trigger an immunogenic cell death that stimulates an anti-tumor immune response.

Comparison of Wild-Type Adenovirus and Our Cretostimogene Constructs



Overview of Cretostimogene's Replication Selectivity in Healthy Versus Cancerous Cells with Defective Rb-Pathway

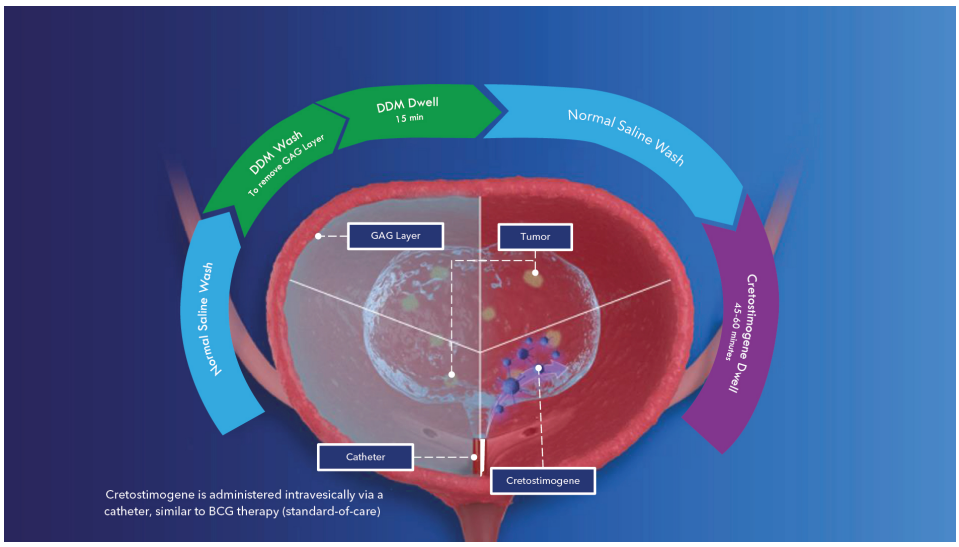


Cretostimogene Administration

Prior to the administration of cretostimogene, patients undergo a saline wash and are then pretreated with n-Dodecyl-ß-D-maltoside (DDM) through IVE delivery. DDM is a mild detergent and solubilizing agent used to attenuate the GAG lining of the transitional epithelium and enhance transduction efficiency of adenovirus by urothelial cells. Following DDM wash/dwell and GAG layer attenuation, cretostimogene is IVE-delivered via a catheter. This administration process does not require operating room time nor placement of the patient under anesthesia. Furthermore, this is a similar route of administration as standard-of-care BCG therapy, which urology practices

perform regularly and, thus, we believe will require limited provider re-training versus other NMIBC treatment approaches.

Overview of Cretostimogene's IVE Administration into the Bladder



Cretostimogene Clinical Development

Cretostimogene Monotherapy for High-risk CIS-containing NMIBC after BCG Failure

Overview of BOND-002 Trial Design

The BOND-002 trial was a Phase 2, open-label, single-arm clinical trial of cretostimogene in patients with high-risk NMIBC after BCG failure. Cretostimogene was administered intravesically at 1 x 10^{12} viral particles (VPs) per milliliter to high-risk CIS-containing NMIBC patients, with or without Ta/T1 tumors, and a group of patients with only Ta/T1, that were categorized as having failed BCG therapy and refused radical cystectomy. The trial included a heterogenous mixture of BCG-exposed and BCG-unresponsive patients.

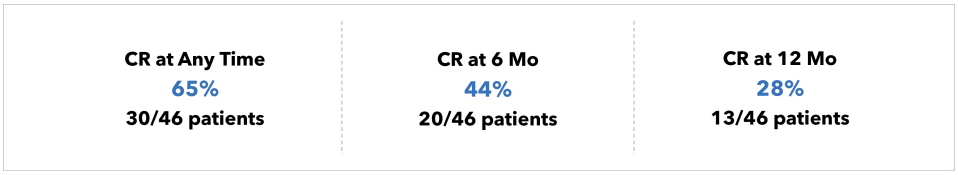
In this study, 46 CIS patients, with or without Ta/T1 disease, and 19 patients with Ta/T1 disease were enrolled. Patients received an initial induction course of six weekly administrations. Patients who achieved a CR at month six received six weekly maintenance doses of cretostimogene using the same concentration. Patients that did not respond to the first induction course were provided a second induction course at month three with no maintenance doses provided at month six. Six weekly follow up doses were then administered at months 12 and 18. In this trial, CR rates were evaluated at various timepoints throughout the study.

Overview of Response Data in BOND-002 Trial

Among the 46 patients with high-risk CIS-containing NMIBC, 30 (65%; 95% CI: 50-78%) patients displayed a CR at any time subsequent to administration of cretostimogene. Four out of 10 (40.0%) patients who did not achieve CR at three months, and who were subsequently re-dosed with cretostimogene at three months demonstrated CR at

six months. The DOR to treatment was also notable, with 44% and 28% of patients demonstrating a CR at six months and 12 months, respectively. The results of BOND-002 are summarized below.

CR Data from BOND-002 Trial



Overview of Safety Data in BOND-002 Trial

Safety and Tolerability Data from BOND-002 Trial

Top Adverse Events Considered Related to Cretostimogene Administration for all Patients (n=68) by Grade				
	Grade 1	Grade 2	Grade 3	All Grades
Bladder Spasm	9 (13.2%)	3 (4.4%)	-	12 (17.6%)
Haematuria	9 (13.2%)	2 (2.9%)	-	11 (16.2)
Dysuria	4 (5.9%)	5 (7.4%)	1 (1.5%)	10 (14.7%)
Micturition Urgency	5 (7.5%)	4 (5.9%)	-	9 (13.2)
Pollakiuria	5 (7.5%)	1 (1.5%)	-	6 (8.8%)
Urinary Tract Infection	1 (1.5%)	3 (4.4%)	-	4 (5.9%)
Fatigue	3 (4.4%)	1 (1.5%)	-	4 (5.9%)
Influenza-like Illness	3 (4.4%)	-	-	3 (4.4%)
Influenza	2 (2.9%)	-	-	2 (2.9%)
Bladder Discomfort	1 (1.5%)	-	-	1 (1.5%)
Hypotension	-	-	1 (1.5%)	1 (1.5%)

In addition to the 65 patients enrolled per the trial protocol, the safety results above included three additional patients, two who were dosed with cretostimogene for compassionate, single-use patient INDs and one more determined not to have baseline NMIBC retrospectively. Cretostimogene was generally well-tolerated and most TRAEs were limited to Grade 1 to 2, only two Grade 3 TRAEs involving dysuria and hypotension (both of which were resolved), and no Grade 4 or 5 TRAEs. Furthermore, eight SAEs were reported but were determined not related to cretostimogene. Adverse events are generally classified as SAEs if they are fatal or life-threatening, result in inpatient hospitalization or prolongation of an existing hospitalization, or result in persistent or significant disability or incapacity, as well as other medically significant events that may jeopardize the patient or require medical or surgical intervention. Regardless of grade, a TRAE can be classified as an SAE if it meets the aforementioned criteria.

Overview of BOND-003 Trial Design

BOND-003 is a global, open-label, single-arm Phase 3 clinical trial which has completed enrollment of 115 patients, designed to evaluate the safety and efficacy of cretostimogene as monotherapy in the treatment of patients that have received adequate BCG therapy with high-risk BCG-unresponsive, CIS-containing NMIBC and BCG-unresponsive Ta or T1 papillary tumors. We designed this trial in light of the 2018 FDA guidance which defines BCG-unresponsive disease states and says that single-arm trials that assess CR rate as the primary endpoint, taking DOR into account, may be appropriate for full approval or may require a confirmatory trial following accelerated approval.

The initial induction course of therapy is six weekly doses of cretostimogene containing 1 x 10^{12} VPs per milliliter. Patients who achieve a CR at month three receive maintenance treatments, involving three weekly cretostimogene doses administered at the same concentration every three months for the first 12 months and every six months for the next 24 months. Patients who do not achieve a CR after the first induction course may receive a second induction course of six weekly cretostimogene treatments at month 3, rather than the maintenance course involving three weekly treatments. The primary endpoint of the BOND-003 trial is CR at any time subsequent to induction. We

have completed enrollment for this trial, reported interim data in November 2023 and expect to report topline data by the end of 2024.

Enrollment of Additional Cohort in BOND-003 Trial

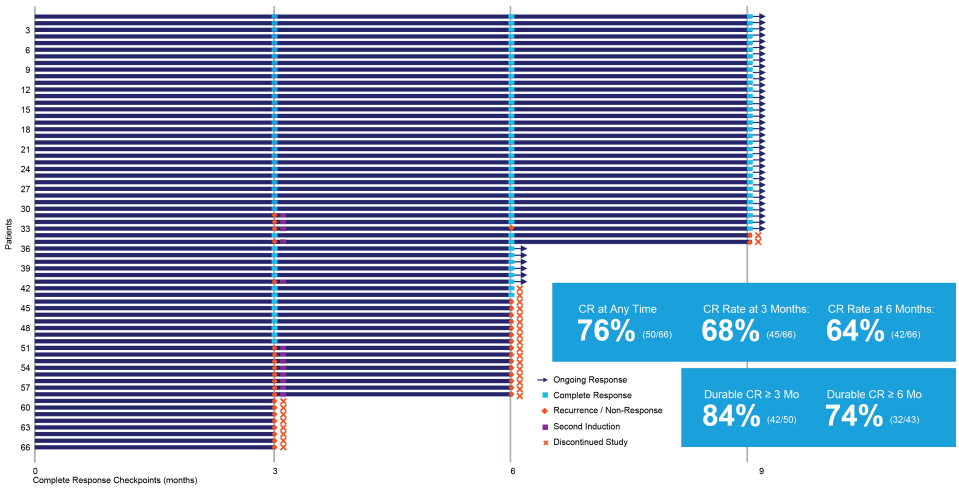
We intend to enroll an additional cohort of up to 75 patients to evaluate the safety and efficacy of cretostimogene as a monotherapy in the treatment of patients with high-risk BCG-unresponsive NMIBC, high-grade Ta or T1 without CIS that have received adequate BCG therapy. The primary endpoint of this cohort is overall event-free survival (EFS), with secondary endpoints including safety, high-grade recurrence-free survival (RFS), low-grade RFS, progression-free survival (PFS), cystectomy-free survival, and bladder cancer specific survival.

Overview of Interim Response Data from BOND-003 Trial

Interim data for BOND-003 were reported at the 24th Annual Meeting of SUO on November 30, 2023. As of the October 5, 2023 efficacy data cutoff, 50 of the 66 (75.7%; 95% CI: 63-85%) evaluable patients achieved a CR at any time after the administration of cretostimogene. In addition, as of the data cutoff, 45 out of 66 (68.2%) patients achieved a CR at three months and 42 out of 66 (63.6%) patients achieved a CR at six months. Four out of 13 (30.8%) patients who did not achieve a CR at three months, and who were subsequently re-dosed with cretostimogene at three months demonstrated a CR at six months. One additional patient who was re-dosed at three months and did not achieve a CR at six months stayed on trial at the recommendation of the principal investigator and achieved a CR at nine months. We have excluded this patient's CR from the results because under the protocol, a patient who fails to achieve a CR at three months and six months would be discontinued from the trial.

Of those 50 patients who achieved a CR at any time, 42 out of 50 (84.0%) maintained their response for at least three months and 32 out of 43 (74.4%) evaluable responders maintained their response for at least six months. Seven patients had yet to reach the minimum duration of response evaluation and were excluded from the assessment for durable CR lasting at least six months. The median age of evaluable patients was 73 years old (range: 49-90), of which 76% were male. Patients had received between seven and 47 prior installations of BCG therapy and 80% had an Eastern Cooperative Oncology Group (ECOG) score of zero. ECOG is a measure of a patient's level of general function and capability of self-care with a zero score meaning that a patient is fully active and able to carry on pre-disease performance without restriction. The chart below presents a summary of interim results observed in patients enrolled in the BOND-003 trial as of the data cutoff.

Overview of Interim Results from BOND-003 Trial



Overview of Interim Safety Data from BOND-003 Trial

Cretostimogene was generally well-tolerated in this trial as of the September 8, 2023 safety data cutoff, with mostly Grade 1 or Grade 2 adverse events reported and no Grade 3 or higher TRAEs reported. There were no treatment discontinuations due to TRAEs, and no deaths were reported. Two patients (1.8%) had SAEs, including Grade 2 noninfective cystitis, and Grade 2 clot retention, both of which resolved. Interim results from this trial may differ from future results of the trial as more patient data become available.

Combination of Cretostimogene Plus Pembrolizumab for High-risk BCG-unresponsive CIS-containing NMIBC

Overview of CORE-001 Trial Design

CORE-001 is a Phase 2 single-arm, open-label clinical trial of cretostimogene administered in up to 35 patients with high risk, BCG-unresponsive NMIBC that have CIS-containing tumors, in combination with pembrolizumab, following disease resection. Patients that demonstrate a CR after an initial six-week induction phase of weekly cretostimogene administrations, dosed at a concentration of 1 x 10^{12} VP per milliliter, who also receive two, 400 mg doses of pembrolizumab over three months, are given a maintenance course of three weekly doses of cretostimogene at an equivalent VP concentration, along with two doses of pembrolizumab for three months. Trial participants that do not respond to an initial induction course are eligible to receive a second induction course of six weekly administrations over the following three-month period. During the following six months, patients are provided three weekly doses of cretostimogene every three months for six months, in addition to pembrolizumab every six weeks, with longer-term follow up administration of three weekly doses every six months for 12 months, along with pembrolizumab every 6 weeks. The primary endpoints of the CORE-001 trial is CR at 12 months, with secondary endpoints including CR at any time, DOR and PFS. We have entered into a clinical trial collaboration and supply agreement with Merck providing at no-cost supply of pembrolizumab for use in CORE-001 (which agreement also provides for the joint ownership of clinical trial data but has no additional financial obligations and terminates upon conclusion of the trial).

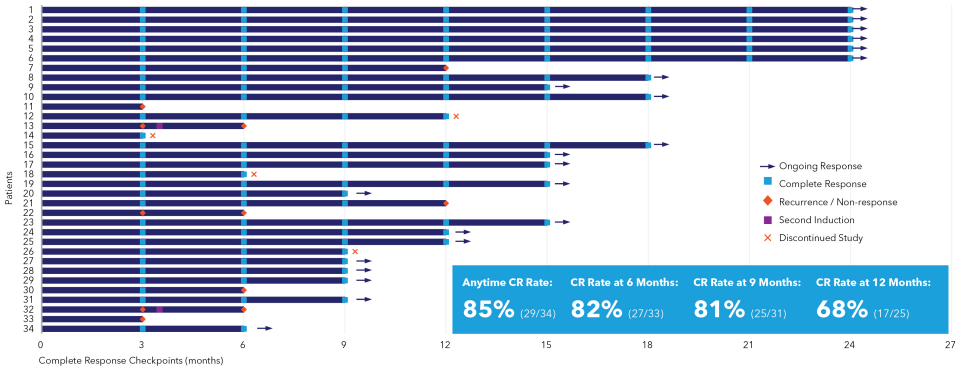
The dosing schedule of cretostimogene in CORE-001 is similar to BOND-003, while pembrolizumab is administered pursuant to its approved dosing schedule.

Overview of Interim Clinical Results in Our Ongoing CORE-001 Trial

Interim results from the CORE-001 demonstrated that, as of the March 3, 2023 data cutoff, 29 of the 34 (85%; 95% CI: 68-94%) evaluable patients displayed a CR at any time subsequent to completion of induction therapy. Moreover, administration of cretostimogene has also resulted in durable responses, with 82% (n=27/33) of the

evaluable patients maintaining a CR at six months and 68% (n=17/25) of evaluable patients maintaining a CR at 12 months, each as of the cutoff date. In the chart below is presented a summary of the interim results observed in patients enrolled in the CORE-001 trial.

Overview of Interim Results from CORE-001 Trial



We anticipate reporting additional durability data in the first half of 2024.

Overview of Interim Safety Data from Ongoing CORE-001 Trial

Similar to the results achieved in the BOND-002 trial, cretostimogene was observed to be generally well tolerated. As of the January 31, 2023 safety data cutoff, most cretostimogene-related adverse events were transient, localized Grade 1 or 2 local urinary tract related issues. As of the safety data cutoff, one Grade 2 SAE (urinary retention) deemed related to cretostimogene was reported and resolved. There have been no discontinuations from the trial deemed related to cretostimogene. As of the data cutoff, there were two Grade 3 SAEs related to pembrolizumab (adrenal insufficiency and immune-mediated hepatitis). As of the data cutoff, there were four Grade 3 adverse events related to pembrolizumab which led to a discontinuation; one patient resumed dosing of pembrolizumab after missing a single dose. Subsequent to the safety data cutoff, there were three adverse events related to pembrolizumab which led to discontinuation of pembrolizumab. The observed Grade 3 SAEs related to pembrolizumab are consistent with immune-related adverse events observed in prior anti-PD1 CPI trials.

Cretostimogene Monotherapy for Intermediate-risk NMIBC following TURBT

Phase 3 PIVOT-006 Clinical Trial

We initiated PIVOT-006 in November 2023, which is a randomized Phase 3 trial intended to assess the safety and efficacy of adjuvant cretostimogene when administered as monotherapy to patients with intermediate-risk NMIBC following TURBT. This is a two-arm trial enrolling up to 426 intermediate-risk NMIBC patients, one arm to be administered cretostimogene following the standard of care TURBT with the second arm receiving the standard of care TURBT only. The initial induction course is six weekly doses of cretostimogene containing $1x10^{12}$ VPs per milliliter. We expect that patients who are recurrence-free at month three will receive a maintenance course involving three weekly cretostimogene doses administered at the same concentration, in months 3 and 6, followed by single weekly doses in months 9 and 12. The primary endpoint of this trial is overall RFS, with secondary endpoints including RFS at 12 and 24 months and PFS. RFS is based on time to last cystoscopic evaluation or time to disease relapse where relapse is defined as any grade bladder cancer recurrence. The first patient was dosed in February 2024. We expect to complete enrollment for this trial in the first half of 2026.

Planned Clinical Trial

Phase 2 CORE-008 Clinical Trial

The planned study is an open-label multi-cohort Phase 2 trial intended to assess the safety and clinical outcomes of cretostimogene in treating patients with high-risk NMIBC including BCG-exposed and BCG-naïve NMIBC patients. Each cohort is expected to enroll at least 60 patients. BCG-exposed patients are classified as those NMIBC patients with persistent, recurrent or progressive disease after BCG treatment but do not meet the specific disease classification criteria to be designated BCG-unresponsive. BCG-naïve patients are classified as those NMIBC patients who have not received any prior BCG therapy. After an induction course of therapy of six weekly doses of cretostimogene containing 1×10^{12} VPs per milliliter, we expect that patients who achieve a CR will receive a maintenance course at the same concentration every three months until disease recurrence. We expect that patients who do not achieve a CR after the initial induction course will receive a second induction course at the same concentration followed by the same maintenance course if they achieve a CR. The targeted efficacy endpoints of this trial are expected to include CR at any time following induction, CR at 12 months, DOR and PFS. We expect to initiate this trial in the second half of 2024.

Additional Clinical Trial Evaluations in MIBC

MIBC is associated with significantly higher mortality than NMIBC, the five-year mortality rate for patients with MIBC ranging from approximately 66% to 95% depending on disease stage. As such, the delay of disease progression is of particular significance to the estimated 20% to 25% of newly diagnosed bladder cancer patients with MIBC as well as those high-risk NMIBC patients that progress to MIBC. Moreover, the annual cost of care for patients with MIBC is estimated to be approximately 2.5 times the annual cost of care for patients with NMIBC.

Systemic administration of cisplatin is often used as neoadjuvant chemotherapy in the treatment of MIBC. However, as many as 50% of patients are ineligible to receive cisplatin because of existing co-morbidities such as decreased renal function or neuropathy in which case CPIs are the default standard of care. We are currently evaluating the use of cretostimogene in combination with the CPI nivolumab as a treatment for MIBC, including by our support of CORE-002, a single-arm exploratory investigator-sponsored clinical trial of 30 cisplatin-ineligible patients with no evidence of distant metastases prior to radical cystectomy. Cretostimogene induction therapy is accompanied by IV nivolumab dosed week 2 and week 6 followed by TURBT or cystectomy. The primary endpoint in this trial is safety; secondary endpoints include evaluations of pathological CR (pCR), RFS and changes in inflammatory status of tumors after combination therapy.

As of the March 31, 2023 CORE-002 data cutoff, among the 15 evaluable patients, the combination of cretostimogene and nivolumab had produced a pCR in eight patients, or a pCR rate of 53% (n=8/15). An additional patient had a negative post-treatment biopsy but refused radical cystectomy. Cretostimogene has been generally well-tolerated among trial participants as of the data cutoff. Immune related AE was seen in one patient, who had Grade 2 autoimmune thyroiditis. There was no delay in time to radical cystectomy and no unexpected surgical complications from treatment.

Manufacturing

We leverage third-party manufacturers to support the manufacturing of cretostimogene for clinical trials and, if we receive regulatory approval, we intend to rely on such third parties for commercial manufacture. We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We believe this strategy will enable us to maintain a nimble, efficient and effective working model without making significant internal capital investments. We are currently focused on developing high-yield and scalable processes and analytical methods for the manufacture of cretostimogene. We believe our current manufacturing scale could support commercial demand for cretostimogene to treat high-risk, BCG-unresponsive NMIBC patients, if approved. We work with a third-party manufacturer for the production of cretostimogene and a third-party manufacturer for the production of DDM. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have any long-term supply agreements in place. In order to de-risk our supply chain, and as we advance toward potential commercialization, we intend to enter into long-term supply agreements as well as evaluate additional product manufacturing sources.

We have established strong in-house CMC capabilities consisting of expertise in process and analytical development and manufacturing, spanning across different modalities including viruses. To complement our in-house CMC capabilities, we have established a CMC Advisory Board, consisting of some of the most respected names in the industry. This advisory group is chaired by Dr. Richard Rutter, Ph.D., formerly Executive Vice President of Biotherapeutics Pharmaceuticals Sciences at Pfizer, and includes Dr. Daniel Takefman, Ph.D., formerly chief of the gene therapy branch at the FDA; Dr. Richard Peluso, Ph.D., formerly Vice President, Biologics and Vaccines, Bioprocess R&D at Merck; and Dr. Victoria Sluzky, Ph.D., formerly Senior Vice President, Technical Development for BioMarin Pharmaceuticals. In combination with the CMC Advisory Board's experience and strong internal capabilities, we strive to build a sustainable and effective CMC organization.

Competition

We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. In addition, many biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies, technologies, and data emerge within the field of oncology and, furthermore, within the treatment of bladder cancer.

We will continue to face competition from current standard of care treatments, including BCG. To the extent Merck or another manufacturer increases the supply of BCG, there may be less demand for alternative treatments such as cretostimogene in BCG-naïve or BCG-exposed patients. In addition, there are numerous companies that have commercialized or are developing treatments for NMIBC, including Bristol Meyers Squibb, enGene Inc., Gilead Sciences, Inc., Hoffman-La Roche AG (Roche), ImmunityBio Inc., Johnson & Johnson Inc., Merck, Protara Therapeutics, Inc., Pfizer, Inc., and UroGen Pharma, Inc.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, regulatory processes, and marketing than we do. Mergers and acquisitions activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also 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.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors successfully develop and commercialize products that are safer, more effective, better-tolerated, or of greater convenience or economic benefit than our proposed product offering. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Commercialization

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. If we obtain FDA approval for cretostimogene, we intend to build in-house sales and marketing capabilities to commercialize cretostimogene in the United States, and potentially other regions, and expect to rely on third parties for distribution. While the number of patients suffering from bladder cancer is large and growing, a significant portion of large urology practices are concentrated in a relatively small number of major metropolitan areas and urology physician groups. We believe this concentration will potentially enable us to efficiently reach a large portion of our estimated addressable market with a relatively small commercial footprint. Importantly, urology practices are already deeply familiar with the administration of TURBT followed by intravesical administration of BCG in NMIBC patients. Cretostimogene is similarly designed to be administered intravesically and we believe will not require urology practices to retrain or learn a new administrative method. Outside of the United States, we may,

where appropriate, pursue development and commercialization relationships, including strategic alliances and licensing, with pharmaceutical companies and other strategic partners, to maximize the commercial potential of cretostimogene in such countries, such as with our agreements with Kissei Pharmaceutical Co., Ltd. and Lepu Biotech Co., Ltd. described below.

License and Collaboration Agreements

Kissei Pharmaceutical Co., Ltd. License and Collaboration Agreement

In March 2020, and as amended September 2022, we entered into a license and collaboration agreement (the Kissei Agreement) with Kissei Pharmaceutical Co., Ltd. (Kissei), under which we granted to Kissei an exclusive license to certain intellectual property rights in Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, Nepal, Pakistan, Palau, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam (the Kissei Territory), for Kissei to develop and commercialize, but not manufacture, cretostimogene in combination with DDM (the Licensed Product) for all uses in oncology indications for which marketing approval is being sought. Under the Kissei Agreement, we and Kissei agreed to use commercially reasonable efforts to collaborate on clinical development activities in the Kissei Territory and each party is responsible for conducting the applicable activities pursuant to an agreed development plan. Kissei is responsible for the costs of developing the Licensed Product in the Kissei Territory, and we are responsible for the costs of developing the Licensed Product outside the Kissei Territory, provided that Kissei is responsible for a low-double digit percentage and we are responsible for a high-double digit percentage of the cost of development activities that cannot be attributed solely to the Kissei Territory or outside the Kissei Territory. We are obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from us. Kissei is responsible for commercializing the Licensed Product in the Kissei Territory and is obligated to use commercially reasonable efforts to seek regulatory approval for and commercialize at least one Licensed Product in a specified indication. Until a certain period of time has passed after the first regulatory approval of the Licensed Product, we are prohibited from commercializing certain competing products worldwide and Kissei is prohibited from researching, developing or commercializing certain competing products worldwide.

Kissei paid to us a one-time upfront payment of $10.0 million and, in connection with the entry into the Kissei Agreement, purchased $30.0 million worth of shares of our Series D redeemable convertible preferred stock as part of our Series D financing. Kissei is obligated to make development, regulatory and commercial milestone payments of up to $100.0 million. We have also agreed to pay Kissei a royalty on net sales of Licensed Product outside the Kissei Territory and outside the Lepu Territory (as described below), including on any U.S. sales, in a low-single digit percentage, subject to certain reductions. We are entitled to receive a royalty on net sales of Licensed Product in the Kissei Territory in the mid-twenties percentage, subject to certain capped reductions. Also, Kissei has the right to offset the royalty payments due to us with respect to the cost for the supply of Licensed Product sold by us to Kissei, and to indefinitely carry forward credits for any excess supply amounts paid over royalty amounts owed in a given quarter. We are entitled to receive a specified minimum percentage of royalties on net sales of a given Licensed Product in a given country and a given quarter, unless, if for such Licensed Product in such country and such quarter, Kissei has taken the maximum allowable reductions and the ratio of the cost for the supply of Licensed Product to the sales price for Licensed Product exceeds a low-double digit percentage threshold, then we shall receive no royalties on the net sales of such Licensed Product in such country and such quarter. Kissei's and our royalty obligations will expire on a Licensed Product-by-Licensed Product and country-by-country basis on the later of twelve years from the date of first commercial sale of such Licensed Product in such country or when there is no longer a valid patent claim covering such Licensed Product in such country.

The Kissei Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country basis when there is no remaining royalty or milestone payment obligation due to a party with respect to such Licensed Product in such country. Following expiration of the Kissei Agreement in its entirety, the licenses we granted to Kissei will become non-exclusive, fully-paid royalty-free and irrevocable and Kissei will have the right to negotiate directly with our product suppliers for the direct supply of Licensed Product to Kissei. The Kissei Agreement may be terminated either by Kissei or by us in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, insolvency or similar circumstances. In addition, we have the right to terminate the Kissei Agreement in the event that Kissei commences a legal action challenging the validity, enforceability or scope of any licensed patents under the Kissei Agreement. Kissei may terminate the Kissei

Agreement at will upon specified written notice. Additionally, Kissei may terminate the Kissei Agreement for our willful and malicious misconduct that results in substantial and irreparable harm to the commercial value of the Licensed Products in the Kissei Territory and upon any such termination, the licenses we granted to Kissei will become royalty-free and fully paid-up and Kissei will have the right to negotiate directly with our contract manufacturing organizations for the supply of Licensed Product. Upon termination of the Kissei Agreement for any other reason all rights and licenses granted to Kissei to develop and commercialize the product under the Kissei Agreement will terminate, subject to certain rights to sell existing inventory of Licensed Products by Kissei and its sublicensees. Upon termination of the Kissei Agreement for Kissei's breach, any sublicenses granted by Kissei may, upon our discretion, continue.

Lepu Biotech Co., Ltd. Development and License Agreement

In March 2019, we entered into a development and license agreement (the Lepu Agreement) with Lepu Biotech Co., Ltd. (Lepu), under which we granted an exclusive license to Lepu to develop, manufacture and commercialize cretostimogene and/or DDM to treat and/or prevent cancer in mainland China, including Hong Kong and Macau (the Lepu Territory). Under the Lepu Agreement, Lepu is responsible for using commercially reasonable efforts to develop cretostimogene and DDM in the Lepu Territory, including by performing clinical development activities pursuant to an agreed development plan, and we are obligated to provide Lepu with reasonably requested information, know-how and assistance at Lepu's cost and expense. Additionally, Lepu is obligated to meet a certain clinical diligence milestone by a specified date in 2024. We are also obligated to use commercially reasonable efforts to supply Lepu with its requirements of cretostimogene and DDM for its development activities at Lepu's cost and to periodically provide Lepu with manufacturing documentation and, at Lepu's cost, reasonably requested assistance related to the manufacture of clinical and, if applicable, commercial supplies of cretostimogene and DDM. Lepu is obligated to use commercially reasonable efforts to commercialize at least one of cretostimogene and/or DDM and achieve the first commercial sale of such product in the Lepu Territory within specified time periods after receipt of marketing authorization approval therefor.

Lepu paid to us a one-time upfront payment of $4.5 million and is obligated to make regulatory milestone payments of up to $2.5 million and commercial milestone payments of up to $57.5 million. We are entitled to receive a high single-digit royalty on net sales of cretostimogene and/or DDM sold in the Lepu Territory, subject to a specified reduction. Lepu's royalty obligations will expire upon termination of the Lepu Agreement. Lepu may terminate the Lepu Agreement for any reason upon specified prior written notice. The agreement may be terminated either by Lepu or by us in the event of an uncured material breach by the other party. In addition, we have the right to terminate the agreement in the event that Lepu commences or requests a legal action challenging the validity, enforceability or scope of any licensed patents. Upon termination of the agreement for any reason, all rights and licenses granted to Lepu to develop and commercialize cretostimogene and DDM under the agreement will terminate, and Lepu will be obligated to provide to us all data and results pertaining to cretostimogene and DDM products and assign and transfer to us all regulatory filings, manufacturing documentation and marketing authorization approvals for cretostimogene and DDM. In the event that Lepu has any ongoing clinical trials with respect to cretostimogene and/or DDM as of the effective date of termination, at our request, Lepu is obligated to either promptly transition such clinical trials to us or continue to conduct and complete such clinical trials, at our expense.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and their methods of use are an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. We have obtained patents and filed patent applications in the United States and other countries relating to certain of our proprietary technology, inventions, improvements, and product candidates, and are pursuing additional patent protection for them. We endeavor to protect the proprietary technologies that we believe are important to our business, including pursuing and maintaining patent protection intended to cover cretostimogene, its methods of use, related technologies, and other inventions that are important to our business. In addition to patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our proprietary method of manufacturing cretostimogene. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available. For example, under the Biologics Price Competition and

Innovation Act of 2009 (BPCIA), we believe that cretostimogene or any future product candidates we may develop, if approved as a biological product under a BLA, should qualify for the 12-year period of reference product exclusivity.

As of December 31, 2023, we own five patent families comprising five issued U.S. patents, three issued foreign patents in Japan and Singapore, three pending U.S. non-provisional patent applications, and 18 pending patent applications in jurisdictions outside of the United States.

With regard to cretostimogene, we own three issued U.S. patents and three issued patents in Japan and Singapore with claims covering methods of use using cretostimogene, including claims covering treatment schedules and combination therapy. These issued patents are expected to expire between 2036 and 2038, without accounting for potentially available patent term adjustments or extensions. We also own three pending U.S. applications and 18 related pending applications with claims covering methods of use using cretostimogene (including claims covering treatment schedules and combination therapy) in Australia, New Zealand, Japan, South Korea, China, Singapore, Hong Kong, and before the European Patent Office, and any patents that issue from these applications are expected to expire between 2036 and 2038, without accounting for potentially available patent term adjustments or extensions.

We expect to file additional patent applications in support of current and new product candidates as well as new platform and core technologies.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of cretostimogene, our future product candidates, and their methods of use, as well as successfully defending any such patents against third-party challenges, preserving the confidentiality of our trade secrets, and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

The terms of individual patents depend upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing 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 U.S. Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over another patent of ours. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits patent term restoration as compensation for a portion of the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the subject drug candidate is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe, Japan and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment that such extensions should be granted, and if granted, the length of such extensions.

The actual protection afforded by a patent varies on a claim by claim and country by country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

In addition to patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, aspects of our manufacturing processes for cretostimogene. However, trade secrets can be difficult to protect. Although we take steps

to protect our proprietary information, including restriction to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, and potential collaborators, such individuals may breach such agreements and disclose our proprietary information including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

For more information regarding the risks related to our intellectual property, please see the section titled "Risk Factors—Risks Related to Our Intellectual Property."

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. 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 (GLPs), and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board (IRB) or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations (GCPs), to evaluate the safety, purity and potency of the product candidate for its intended use;
- submission to the FDA of a 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 (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.

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

Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough 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 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.

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 (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. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, for single source and innovator multiple source drugs, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. 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.

Most recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

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

Data Privacy and Security Laws

Numerous state, federal, and foreign laws, regulations and standards govern the collection, use, access to, confidentiality, and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to

complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees and Human Capital Resources

As of December 31, 2023, we had 61 employees, all of whom were full-time and 44 of whom were engaged in research and development activities. Thirteen of our employees hold Ph.D. or M.D. degrees. All research and development personnel and our administrative team are based in and around Irvine, CA. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

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

Available Information

Our internet address is https://cgoncology.com/. Our investor relations website is located at https://ir.cgoncology.com/. We make available free of charge on our investor relations website under "SEC Filings" our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors' and officers' Section 16 reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the SEC. They are also available for free on the SEC's website at www.sec.gov.

We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included on our investor relations website. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, together with the other information contained in this Annual Report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision regarding our securities. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition. In this section, we first provide a summary of the principal risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

Summary of Risks Related to Our Business

- We have a relatively limited operating history, have incurred significant operating losses since our inception, and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.
- We currently depend entirely on the success of cretostimogene, which is our only product candidate. If we are unable to advance cretostimogene in clinical development, obtain regulatory approval and ultimately commercialize cretostimogene, or experience significant delays in doing so, our business will be materially harmed.
- Cretostimogene is based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval, if at all.
- Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of prior preclinical studies and early clinical trials are not necessarily predictive of future results. Cretostimogene or any future product candidates may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.
- Use of cretostimogene or any future product candidates could be associated with adverse side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon cretostimogene or any future product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects.
- We face significant competition, and if our competitors develop and commercialize technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than cretostimogene or any future product candidates we develop, our business and our ability to develop and successfully commercialize products will be adversely affected.
- We rely on third parties to conduct our clinical trials and preclinical studies, and these third parties may not perform satisfactorily, which could delay, prevent, or impair our development or commercialization efforts.
- We rely on third parties for the manufacture and shipping of cretostimogene for clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of cretostimogene or future product candidates or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.
- If we are unable to obtain, maintain, and enforce patent or other intellectual property protection for cretostimogene or any future product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties

could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize cretostimogene or any future product candidates, may be adversely affected.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a relatively limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a relatively limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2010, have no products approved for commercial sale and have not generated any revenue from the sale of our products. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, conducting research, preclinical studies and clinical trials for our product candidate, cretostimogene, establishing our intellectual property portfolio, establishing arrangements with third parties for the manufacture of cretostimogene and supply of related raw materials, and providing general and administrative support for these operations. We have not yet demonstrated the ability to successfully complete any clinical trial beyond Phase 2, obtain regulatory approvals, manufacture products at commercial scale or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We do not have any products approved for sale and have not generated any revenue from product sales. If we are unable to successfully develop, obtain requisite approval for and commercialize cretostimogene or any future product candidates, we may never generate revenue. Our net losses were $48.6 million and $35.4 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $129.9 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development activities and from general and administrative costs associated with our operations. Cretostimogene and any future product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize cretostimogene and any future product candidates, as well as operate as a public company.

To become and remain profitable, we must succeed in developing, obtaining regulatory approvals for, and eventually commercializing 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 cretostimogene and any future product candidates, acquiring additional product candidates, obtaining regulatory approval for cretostimogene and any future product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials of cretostimogene and potentially seek regulatory approval for cretostimogene and any future product candidates we may develop. In addition, if we are able to progress cretostimogene through development and commercialization, we expect to be required to make milestone and royalty payments pursuant to various license or collaboration agreements with third parties. If we obtain regulatory approval for cretostimogene or any future product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reliably estimate the actual amount of capital necessary to successfully complete the development and commercialization of cretostimogene or any future product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations through 2027. In particular, we expect that our existing cash, cash equivalents and marketable securities will allow us to complete the ongoing BOND-003 and CORE-001 clinical trials, complete enrollment for the PIVOT-006 clinical trial, and initiate and report topline data for our planned CORE-008 clinical trial. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently 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. Our existing capital, may not be sufficient to complete development of cretostimogene, or any future product candidates, and we will require substantial capital in order to advance cretostimogene and any future product candidates through clinical trials, regulatory approval and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds may be adversely impacted by global economic conditions, disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, and diminished liquidity and credit availability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. 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 commercialization efforts, or even cease operations. We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses, and other similar arrangements. 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 cretostimogene or any future product candidates.

Our future capital requirements will depend on many factors, including, but not limited to:

- the initiation, type, number, scope, progress, expansions, results, costs and timing of clinical trials and preclinical studies of cretostimogene and any future product candidates we may choose to pursue, including the costs of modification to clinical development plans based on feedback that we may receive from regulatory authorities and any third-party products used as combination agents in our clinical trials;
- the costs and timing of manufacturing for cretostimogene or any future product candidate, including commercial manufacturing at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages;
- the costs, timing and outcome of regulatory meetings and reviews of cretostimogene or any future product candidates in any jurisdictions in which we or our current or any future collaborators may seek approval for cretostimogene or any future product candidates;
- the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights;

- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, chemistry, manufacturing and control (CMC), quality and commercial personnel;
- the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;
- the costs and timing of establishing or securing sales and marketing capabilities if cretostimogene or any future product candidate is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- our ability and strategic decision to develop future product candidates other than cretostimogene, and the timing of such development, if any;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies and potentially identifying future product candidates is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize cretostimogene or any future product candidates. If approved, cretostimogene and any future product candidates may not achieve commercial success. We expect that our commercial revenue, if any, will initially be derived from sales of cretostimogene, which we do not expect to be commercially available for several years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events or otherwise.

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 cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

We currently depend entirely on the success of cretostimogene, which is our only product candidate. If we are unable to advance cretostimogene in clinical development, obtain regulatory approval and ultimately commercialize cretostimogene, or experience significant delays in doing so, our business will be materially harmed.

We currently only have one product candidate, cretostimogene, which is in Phase 3 clinical development. Our business presently depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize cretostimogene in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. The success of cretostimogene will depend on several factors, including the following:

- successful initiation and enrollment of clinical trials and completion of clinical trials with favorable results;
- acceptance of regulatory submissions by the U.S. Food and Drug Administration (FDA) or comparable foreign regulatory authorities for the conduct of clinical trials of cretostimogene and of our proposed designs of planned clinical trials of cretostimogene;
- the frequency and severity of adverse events observed in clinical trials and preclinical studies;
- maintaining and establishing relationships with contract research organizations (CROs) and clinical sites for the clinical development of cretostimogene, and ability of such CROs and clinical sites to comply with clinical trial protocols, Good Clinical Practices (GCPs) and other applicable requirements;
- demonstrating the safety, purity and potency (or efficacy) of cretostimogene to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities;
- receipt and maintenance of regulatory approvals from applicable regulatory authorities, including approvals of Biologics License Applications (BLAs) from the FDA;
- maintaining relationships with our third-party manufacturers and their ability to comply with current Good Manufacturing Practices (cGMPs) as well as timely making arrangements with our third-party manufacturers for, or establishing our own, commercial manufacturing capabilities at a cost and scale sufficient to support commercialization;
- establishing sales, marketing and distribution capabilities and launching commercial sales of cretostimogene, if and when approved, whether alone or in collaboration with others;
- obtaining, maintaining, protecting and enforcing patent and any potential trade secret protection or regulatory exclusivity for cretostimogene;
- maintaining an acceptable safety profile of cretostimogene following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell cretostimogene; and
- acceptance of our products, if approved, by patients, the medical community and third-party payors.

If we are unable to develop, obtain regulatory approval for, or if approved, successfully manufacture and commercialize cretostimogene, or if we experience delays as a result of any of the above factors or otherwise, our business would be materially harmed.

Cretostimogene is based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval, if at all.

We have concentrated our research and development efforts on cretostimogene, and our future success largely depends on the successful development of the oncolytic approach underlying this product candidate. In particular, cretostimogene is an engineered adenovirus designed to replicate and eliminate cancer cells while also stimulating an

anti-tumor immune response. To our knowledge, there are no FDA-approved products for the treatment of cancer that utilize a replication-competent adenovirus.

We expect the novel nature of cretostimogene to create further challenges in obtaining regulatory approval. Few viral immunotherapies have been approved globally or by the FDA to date. While the first oncolytic viral immunotherapy, talimogene laherparepvec (Imlygic, Amgen), has received FDA approval, regulatory agencies have reviewed relatively few viral immunotherapy product candidates such as cretostimogene. This may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. Further, any viral immunotherapies that are approved may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

In addition, cretostimogene is a live, gene-modified virus for which the FDA and other comparable foreign regulatory authorities and other public health authorities, such as the Centers of Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. We may also experience delays in transferring our process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Cretostimogene or any future product candidates may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.

Drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned, including whether we are able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process, including due to factors that are beyond our control. Despite promising preclinical or clinical results, cretostimogene or any other future product candidate can unexpectedly fail at any stage of clinical or preclinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of cretostimogene, any future product candidate, or a competitor's product candidate in the same class may not predict the results of later clinical trials of cretostimogene or any future product candidate, and interim, topline or preliminary results of a clinical trial are not necessarily indicative of final results. Cretostimogene or any future product candidate in later stages of clinical trials may fail to show the desired characteristics despite having progressed through preclinical studies and initial clinical trials. 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.

Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up; our product candidates may fail to demonstrate safety, purity or potency (or efficacy) in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. Based upon negative or inconclusive results, we or any current or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

As a result, we cannot be certain that our ongoing and planned clinical trials or preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of cretostimogene in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or preclinical studies could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining approval from regulatory authorities for the sale of cretostimogene or any future product candidates, we must conduct extensive clinical trials to demonstrate the safety, purity and potency (or efficacy) of the product candidates in humans. In addition, before we can initiate clinical development for any future preclinical 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 CMC and our proposed clinical trial protocol, as part of an Investigational New Drug application(IND) or similar regulatory submission, and we are also required to submit comparable applications to foreign regulatory authorities for clinical trials outside of the United States. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any future product candidates before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays or increase the costs of developing future product candidates.

Moreover, issues may arise that could cause regulatory authorities to suspend or terminate our ongoing or planned clinical trials. Any such delays in the commencement or completion, or the termination or suspension, of our ongoing and planned clinical trials or preclinical studies could significantly affect our product development timelines and product development costs.

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

- inability to obtain animals or materials to initiate and generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining allowance 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;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards (IRBs) or ethics committees (ECs) at clinical trial sites;
- IRBs/ECs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory requirements or guidelines in other countries;
- obtaining sufficient quantities of cretostimogene or any future product candidates and related raw materials and n-Dodecyl-ß-D-maltoside (DDM) or obtaining sufficient quantities of combination therapies or other materials needed for use in clinical trials and preclinical studies;

- patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including patients failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from any future public health concerns;
- patients choosing alternative treatments for the indications for which we are developing cretostimogene or any future product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials or preclinical studies or costs being greater than we anticipate;
- patients experiencing severe or serious unexpected drug-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 cretostimogene or any future 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 third-party manufacturers, delays or failure by our third-party manufacturers or us to make any necessary changes to such manufacturing process, or failure of such third-party manufacturers 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 or guidelines, and are subject to oversight by these governmental agencies and ECs or IRBs at the medical institutions where the 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, including a clinical hold, or termination due to a number of factors, including, among other reasons, failure to conduct the clinical trial in accordance with GCP and other regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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 IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, we and our collaborators are currently conducting, and we, our collaborators and any future collaborators may in the future conduct, clinical trials in foreign countries, which presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients 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 have served and may in the future 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 cretostimogene or any future product candidates.

In addition, we may make formulation or manufacturing changes to cretostimogene or any future product candidate, in which case we may need to conduct additional preclinical studies or clinical trials to bridge our current version of cretostimogene or future product candidate to earlier versions. If we are unable to conduct such studies or trials, or if we otherwise fail to adequately bridge the current versions of our product candidates to earlier versions, then we may be unable to utilize any data we have gathered from studies or trials that evaluated such earlier versions in our planned regulatory submissions, which could delay our programs. For example, in our ongoing studies of cretostimogene we are utilizing materials produced by a different third-party manufacturer than the third-party manufacturer that produced cretostimogene during the initial clinical trials for cretostimogene, and we are unable to demonstrate full comparability between lots produced previously and those produced by our current manufacturer. As a result, we may be required to gather additional data utilizing material produced by our current third-party manufacturer before we are able to submit a BLA for cretostimogene, if ever.

Many of the factors that cause, or lead to, the termination or 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 delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize cretostimogene or our future product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of cretostimogene or our future product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, results of operations and prospects.

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

Successful and timely completion of clinical trials will require that we identify and enroll a specified number of patients for each of our clinical trials. We may not be able to initiate or continue certain clinical trials for cretostimogene or any future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and characteristics of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidates being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials.

Additionally, other pharmaceutical companies targeting bladder cancer are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. The timing of our clinical trials depends, 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. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of cretostimogene or any future product candidates may be delayed. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

In addition, we rely on, and will continue to rely on, CROs 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 have limited influence over their actual performance. We cannot be certain that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in

enrollment, or be required by the FDA or other regulatory authority to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

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

As is the case with oncology drugs generally, it is likely that there may be side effects and adverse events associated with use of cretostimogene or any future product candidates' use. Results of our, our collaborators' or any future collaborators' clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our product candidates when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Moreover, if cretostimogene or any future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their 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, which may limit the commercial expectations for such product candidate if approved. Unacceptable enhancement of certain toxicities may be seen when cretostimogene or any future product candidates are combined with standard of care therapies, or when they are used as single agents. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compounds.

It is possible that as we, our collaborators or any future collaborators test cretostimogene or any future product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread following any regulatory approval, more illnesses, injuries, discomforts and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected in previous trials, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, we are studying cretostimogene in combination with other therapies and may do so for future product candidates, which may exacerbate adverse events associated with such product candidate. Patients treated with cretostimogene or future product candidates may also be undergoing surgical, radiation and 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, our collaborators' or any future collaborators' 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. For example, we expect that some of the patients enrolled in our, our collaborators' or any future collaborators' clinical trials will die or experience major clinical events either during the course of such clinical trials or after participating in such trials.

In addition, if cretostimogene or any future product candidate 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, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to recall a product or change the way such product is administered to patients;

- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance and/or physician adoption of the particular product candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Although we have completed a Phase 2 clinical trial for cretostimogene, we have not as an organization completed later-stage or pivotal clinical trials or submitted a BLA, and we may be unable to do so for cretostimogene or any future product candidates.

We will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market cretostimogene or any future product candidates. Carrying out later-stage clinical trials and the submission of a successful BLA or other comparable foreign regulatory submission is a complicated process. As an organization, we have completed one Phase 2 clinical trial of cretostimogene, and are conducting and plan to conduct additional Phase 3 clinical trials for cretostimogene. We also plan to conduct a number of additional clinical trials of cretostimogene in parallel over the next several years, which may be a difficult process to manage with our limited resources and which may divert attention of management. We have not yet completed any later-stage or pivotal clinical trials for cretostimogene or any other product candidate. We also have limited experience as a company in preparing and submitting marketing applications and have not previously submitted a BLA or other comparable foreign regulatory submission for any product candidate. In addition, we have had limited interactions with the FDA and cannot be certain how many additional clinical trials of cretostimogene or any future product candidate will be required or how such additional trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of a BLA and regulatory approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our ongoing or planned clinical trials could prevent us from or delay us in submitting BLAs or other comparable foreign regulatory submissions for and commercializing our product candidates.

We intend to develop cretostimogene and future product candidates in combination with other therapies, which exposes us to additional risks.

We intend to develop cretostimogene and any future product candidates for use in combination with one or more currently approved cancer therapies. Even if cretostimogene or any future product candidate we develop was to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with cretostimogene or a future product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. The known side effect profile of approved drugs, such as the checkpoint inhibitors we use in combination with cretostimogene, may otherwise negatively affect the results of our trials and could limit the number of patients and physicians who choose to adopt cretostimogene, if approved for use as combination therapy with such drugs. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop cretostimogene or any future product candidate for use in combination with other drugs or biologics. Developing combination therapies using approved therapeutics, as we plan to do for cretostimogene and our future product candidates, also exposes us to additional clinical risks, such as the requirement

that we demonstrate the safety, purity and potency (or efficacy) of each active component of any combination regimen we may develop.

If the FDA or similar foreign regulatory authorities revoke the approval of combination agents, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with cretostimogene or any future product candidate, we may be unable to obtain approval of or market cretostimogene or any future product candidate for combination therapy regimens.

Additionally, if the third-party providers of therapies or therapies in development used in combination with cretostimogene or any future product candidate are unable to produce sufficient quantities for clinical trials or for commercialization of cretostimogene or any future product candidate, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Negative developments in the field of immuno-oncology and, in particular, viral immunotherapy, could damage public perception of any cretostimogene or any future oncolytic product candidates and negatively affect our business.

The commercial success of cretostimogene and any future adenovirus-based product candidates will depend in part on public acceptance of the use of immuno-oncology, and, in particular, viral immunotherapy. Adverse events in clinical trials of cretostimogene or any other adenovirus-based product candidates which we may develop, or in clinical trials of other biopharmaceutical companies developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for cretostimogene or any other adenovirus-based product candidates that we may develop. These events could also result in the suspension, discontinuation or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of viral immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our, our collaborators' or any future collaborators' clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs.

Adverse developments in clinical trials of other immunotherapy products based on viruses, like oncolytic viruses, may result in a disproportionately negative effect for cretostimogene or any future product candidates as compared to other products in the field of infectious disease and immuno-oncology that are not based on viruses. Future negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of cretostimogene or any future product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates.

We may not be successful in our efforts to investigate cretostimogene in additional indications. We may expend our limited resources to pursue a new product candidate or a particular indication for cretostimogene and fail to capitalize on product candidates or indications 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 the development of cretostimogene for specific indications. We may fail to generate additional clinical development opportunities for cretostimogene for a number of reasons, including that cretostimogene may, in indications we are seeking or may seek in the future, be shown to have harmful side effects, limited to no efficacy or other characteristics that suggest it is unlikely to receive marketing approval and/or achieve market acceptance in such potential indications. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications for cretostimogene. Our spending on current and future research and development programs for new product

candidates or additional indications for cretostimogene may not yield any commercially viable product candidates or indications. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may fail to develop such product candidate or indication, or relinquish valuable rights to that product candidate through collaborations, license agreements and other similar arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such indication or product candidate, or negotiate less advantageous terms for any such arrangements than is optimal.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

We are currently conducting and may in the future conduct certain of our clinical trials for cretostimogene or any future product candidate outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are currently conducting, and we or our current or any future collaborators may in the future conduct, one or more of our clinical trials for cretostimogene or any future product candidate outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data from our clinical trials of cretostimogene or any future product candidate, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of such product candidate.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment, and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- diminished protection of intellectual property in some countries; and
- public health concerns or political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

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 interim data by us or by our competitors could result in volatility in the price of our common stock.

In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. Moreover, 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 drug, 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 cretostimogene and any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Changes in methods of the manufacturing or formulation of cretostimogene or any future product candidates may result in additional costs or delay.

As cretostimogene and any future product candidates progress through clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. There can be no assurance that any future manufacturing or formulation changes we may make will achieve their intended objectives, and such changes may also cause cretostimogene or any future product candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or related unfavorable clinical trial results or changes in the CMOs we use to manufacture cretostimogene or any future product candidates could delay initiation or completion of clinical trials, require the conduct of bridging studies or additional clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential regulatory approval and jeopardize our ability to commercialize cretostimogene or any future product candidates, if approved, and generate revenue.

A Breakthrough Therapy designation from the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that cretostimogene or any future product candidates will receive FDA approval.

We have obtained Breakthrough Therapy designation from the FDA for cretostimogene for the treatment of BCG-unresponsive, high risk NMIBC patients with carcinoma in-situ with or without Ta or T1 papillary tumors to improve complete response (CR) and for cretostimogene in combination with pembrolizumab for the treatment of NMIBC unresponsive to BCG, and we may seek additional Breakthrough Therapy designations for cretostimogene or for any future product candidates where we believe the clinical data support such a 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 fast track designation, including eligibility for rolling review of a submitted BLA, if the relevant criteria are met.

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 cretostimogene or any future product candidate may not result in a faster development process, review or approval compared to biologics considered for approval under standard FDA review procedures and does not ensure ultimate approval by the FDA. In addition, though cretostimogene currently qualifies as a Breakthrough Therapy for the treatment of NMIBC unresponsive BGC, the FDA may later decide that cretostimogene no longer meets the conditions for qualification and rescind the designation.

Fast track designation by the FDA for cretostimogene may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that cretostimogene or any future product candidate which may receive fast track designation will receive regulatory approval.

The FDA has granted a fast track designation for cretostimogene for the treatment of BCG-unresponsive, high risk NMIBC patients with carcinoma in-situ with or without Ta or T1 papillary tumors to improve CR, and we may seek fast track designations for other indications or future product candidates. The fast track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, biologics are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. 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. A BLA submitted for a fast track product candidate may also be eligible for rolling review, where 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.

The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate or development program is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Although we have received fast track designation for cretostimogene for the treatment of BCG-unresponsive, high risk NMIBC patients with carcinoma in-situ with or without Ta or T1 papillary tumors to improve CR, and even if we receive additional fast track designations for other indications or any future product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that cretostimogene or any future product candidate that may be granted fast track designation will receive marketing approval in the United States. Many product candidates that have received fast track designation have ultimately failed to obtain approval.

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 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 an accelerated approval for cretostimogene or our future 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 such 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 drug 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 post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such confirmatory studies fail to confirm the drug's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, in December 2022, the Food and Drug Omnibus Reform Act of 2022 was enacted, which, among other things, provided the FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval and additional oversight over confirmatory trials. Under these provisions, the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

Prior to seeking approval for cretostimogene or any future product candidate 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 for accelerated approval or obtain any other form of expedited development, review, or approval. Furthermore, if we decide to submit an application for accelerated approval for cretostimogene or any future product candidate, there can be no assurance that such submission or application will be accepted or that any expedited development, review, or approval will be granted on a timely basis, or at all. The FDA 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 cretostimogene or any future 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.

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, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies 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, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies 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 may also slow the time necessary for new biologics or modifications to approved or licensed 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 employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, future pandemics may lead to similar inspectional or administrative delays. If any future prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory 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.

Risks Related to Our Reliance 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, cretostimogene or any future product candidate and our ability to seek or obtain regulatory approval for or commercialize cretostimogene or any future product candidates may be delayed.

We are dependent on third parties to conduct our clinical trials and preclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs and consultants to conduct our preclinical studies and clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. 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 and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with Good Laboratory Practice (GLP) requirements for certain preclinical studies, as well as GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for cretostimogene and any future product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the clinical 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 preclinical studies or clinical trials before approving our marketing applications, if ever. Further, our clinical trials must be conducted with products produced 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, 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 fail 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 development activities that could harm our competitive position. In addition, principal investigators for our clinical trials have served and may in the future serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA or comparable foreign regulatory authorities of any BLA we submit or any comparable submission. Any such delay or rejection could prevent us from receiving regulatory approval for, or commercializing cretostimogene and any future product candidates.

Our CROs 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, in a timely manner or at all. Switching or adding additional CROs, 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 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, 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, results of operations and prospects.

We rely on third parties for the manufacture and shipping of cretostimogene for clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of cretostimogene or future product candidates or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial-scale manufacturing capabilities. We rely on a third-party manufacturer for the production of cretostimogene and a third-party manufacturer for the production of DDM, and expect to continue to rely on third-party manufacturers for commercial manufacture if cretostimogene or any future product candidates receive regulatory approval. The facilities used by third-party manufacturers to manufacture cretostimogene or any future product candidate must be approved for the manufacture of such product candidate by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit a BLA to the FDA or any comparable submission 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 products. 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 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 of cretostimogene or any future product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market cretostimogene or any future 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 of cretostimogene or any future product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of cretostimogene or any future product candidates.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms, in a timely manner 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 continue clinical trials of cretostimogene or any future product candidates, or a hold on clinical trials of cretostimogene or any future product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for cretostimogene or any future product candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of cretostimogene or any future product candidates; and
- in the event of approval to market and commercialize cretostimogene or any future product candidates, an inability to meet commercial demands for cretostimogene or any future product candidates.

For example, our IND for cretostimogene was previously placed on partial clinical hold by the FDA that was lifted in March 2020, primarily due to CMC-related issues attributable to product supplied by our prior third-party manufacturer, who was purchased by another third-party supplier, resulting in clinical development delays. In addition, we do not have any long-term commitments or supply agreements with our 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 or at all, which increases the risk of failing to timely obtain sufficient quantities of cretostimogene 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 according to our specifications;
- failure to obtain adequate raw materials and other materials required for manufacturing;
- failure to manufacture our product according to our schedule or at all;
- failure to successfully scale up manufacturing capacity, if required;
- 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, cretostimogene and any future product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities.

We also rely on a third party to store and transport cretostimogene at temperatures within a certain range, which is known as "strict cold chain" storage and transportation. Any failure by this third party to store or transport cretostimogene at the appropriate temperature could impair the quality of cretostimogene or cause cretostimogene to become unsuitable for use, which could result in lost inventories, increased costs or delays in clinical development.

Any performance failure on the part of our existing or future manufacturers, suppliers or vendors could delay clinical development or regulatory approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant manufacturing of cretostimogene and DDM. In addition, there are a limited number of manufacturers capable of manufacturing viral therapies such as cretostimogene, and therefore any need to switch third-party manufacturers may result in development and commercialization delays and increase our operating costs. If our existing or future third-party manufacturers and suppliers cannot perform as agreed or cannot fulfill our commercial supply requirements, we may be required to replace such manufacturers or suppliers and we may be unable to replace them on a timely basis or at all. If we later switch third-party manufacturers, we may be unable to demonstrate comparability between lots produced previously and those produced by such new third-party manufacturers, in which case we may be required to gather additional data utilizing material produced by such new third-party manufacturers before we are able to submit a BLA for cretostimogene, if ever.

In addition, our current and anticipated future dependence upon others for the manufacture of cretostimogene or any future product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture cretostimogene and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others, or are disclosed or

used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

We have entered into, and may in the future enter into, collaboration agreements and strategic alliances to maximize the potential of cretostimogene, and we may not realize the anticipated benefits of such collaborations or alliances. We may continue to form collaborations or alliances in the future with respect to cretostimogene or any future product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We have entered into, and may in the future seek to enter into, collaborations, joint ventures, licenses and other similar arrangements for the development or, if approved, commercialization of cretostimogene and any future product candidates due to capital costs required to develop or commercialize such product candidates or otherwise. For example, we have entered into license and collaboration agreements with Lepu Biotech Co., Ltd. (Lepu) and Kissei Pharmaceutical Co., Ltd. (Kissei), pursuant to which we granted Lepu exclusive rights to develop and commercialize cretostimogene and/or DDM in Greater China, including Hong Kong and Macau (the Lepu Territory), and granted Kissei exclusive rights to develop and commercialize cretostimogene in combination with DDM in Japan and other Asian counties (excluding the Lepu territory). We may not be successful in our efforts to establish or maintain such collaborations because our research and development pipeline may be insufficient, future product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view cretostimogene or any future product candidates as having the requisite potential to demonstrate safety, purity and potency (or efficacy), or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time-consuming and complex. Even if we are successful in our efforts to establish or maintain such collaborations, the terms that we agree upon may not be favorable to us. As a result, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property, cretostimogene or any future product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, our current collaborations limit, and potential future collaborations may limit, our control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of cretostimogene or any future product candidates. Our ability to generate revenue from these arrangements will depend on any current or future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license, or strategic transaction, we will achieve an economic benefit that justifies such transaction, and such transaction may not yield additional development product candidates for our pipeline. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of cretostimogene or any future product candidate is delayed, the safety of any such product candidate is questioned, or the sales of cretostimogene, if approved, or an approved future product candidate, are unsatisfactory.

In addition, our current collaborations are, and potential future collaborations may be, terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and, if approved, commercialization of cretostimogene or any future product candidates, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to cretostimogene or any future product candidates, could delay the development and, if approved, commercialization of such product candidates, and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Cretostimogene and any Future Product Candidates

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

Any regulatory approvals that we may receive for cretostimogene or any future product candidates will require the submission of reports to regulatory authorities, subject us to surveillance to monitor the safety and efficacy of the product, 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 cretostimogene or any future product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, if the FDA or a comparable foreign regulatory authority approves cretostimogene or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of approved 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 standards. Failure to comply with regulatory requirements or later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters, adverse publicity requirements or holds on clinical trials;
- refusal by the FDA or other regulatory authorities 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 and the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize cretostimogene or any future 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 cretostimogene or any future product candidates. 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 and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as cretostimogene or any future product candidates, if approved. In particular, a product

may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive regulatory approval for cretostimogene or any future product candidates, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. 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 government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of cretostimogene or any future 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 (or efficacy) of its product.

We believe that any cretostimogene or any future product candidates, if 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 continue to develop.

The commercial success of cretostimogene or any future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors, and others in the medical community.

Cretostimogene and any future product candidates may not be commercially successful. Even if cretostimogene or any future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. The commercial success of cretostimogene or any future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. In particular, given a significant portion of large urology practices are concentrated in a relatively small number of urology physician groups, market adoption by such groups will be an important factor in potential commercial success. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety, including as compared to any more-established products;
- the indications for which cretostimogene or any future product candidates are approved, if any;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;

- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs;
- the effectiveness of our or any current or future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product.

If cretostimogene or any future product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. 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.

The successful commercialization of cretostimogene or any future 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 cretostimogene or any future 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 offer to reimburse patients only 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. 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.

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 cretostimogene or any future product candidates.

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. 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.

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 cretostimogene or any future 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, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. See the section titled “Risk Factors—Risks Related to Our Business Operations and Industry—Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize cretostimogene or any future product candidates and may adversely affect the prices we may set” for additional related information."

We face significant competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If our competitors develop and commercialize their product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than cretostimogene or any future product candidates we develop, our business and our ability to develop and successfully commercialize products may be adversely affected.

The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with cretostimogene. Cretostimogene and any future product candidates we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of indications for which we are developing cretostimogene. In particular, there is intense competition in the oncology field. Our competitors include larger and better-funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions that may be active in oncology research and could be in direct competition with us. We also compete with these organizations to

recruit management, scientists and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling patients for clinical trials and identifying and in-licensing intellectual property related to future product candidates, as well as entering into collaborations, joint ventures, license agreements and other similar arrangements. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

If cretostimogene or any future product candidates are approved, they will compete with surgery, radiation, and drug therapy, including chemotherapy, BCG, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, antibody-drug conjugates, radiopharmaceuticals, immunotherapy, cell-based therapy, and targeted therapy, or a combination of any such methods, either approved or under development, which are intended to treat the same indications that we are targeting or may target, including through approaches that may prove to be more effective, have fewer side effects, be less costly to manufacture, be more convenient to administer or have other advantages over cretostimogene and any future product candidates. To the extent Merck & Co. (Merck) or another manufacturer increases the supply of BCG, there may be less demand for alternative treatments such as cretostimogene in BCG-naïve or BCG-exposed patients. There are numerous companies that have commercialized or are developing treatments for NMIBC that we will compete with, including Bristol Meyers Squibb, enGene Inc., Gilead Sciences, Inc., Hoffman-La Roche AG (Roche), ImmunityBio Inc., Johnson & Johnson Inc., Merck, Protara Therapeutics, Inc., Pfizer, Inc. and UroGen Pharma, Inc.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for cretostimogene or any future product candidate, we will face competition based on many different factors, including the safety and effectiveness of our product candidates, the ease with which our product candidates can be administered, and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. 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 may make cretostimogene or any future product candidates we develop obsolete or noncompetitive before we recover the expense of their development and commercialization. If we are unable to compete effectively, our opportunity to generate revenue from the sale of cretostimogene or any future product candidates we may develop, if approved, could be adversely affected.

If the market opportunities for cretostimogene or any future product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

Cancer therapies are defined by lines of therapy as well as by treatment-naïve or previously-treated status. Often the initial approval for a new therapy is in later lines and subsequent approval in an earlier line may not be feasible. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, including surgery, radiation therapy, targeted therapy, immunotherapy, chemotherapy, hormone therapy, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. In markets with approved therapies, there is no guarantee that cretostimogene or any future product candidate, even if approved, would be approved for second line or first line therapy. This could limit our potential market opportunity. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy.

Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with cretostimogene or any future product candidate, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, publicly available clinical molecular reports, patient foundations, or market research, and may prove to be incorrect. Further, new trials or information may change the estimated incidence or prevalence of these cancers. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of

which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for cretostimogene or any future product candidate, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

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

We have no internal sales, marketing or distribution capabilities, nor have we ever commercialized a product. If cretostimogene or any future product candidate ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. For example, if cretostimogene is approved, we will need to scale up a cost-effective and reliable cold chain distribution and logistics network, which we may be unable to accomplish and which will require us to rely on third-party distributors. Failure to scale up our cold chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for commercial supply.

We have no prior experience as a company with the marketing, sale or distribution of biopharmaceutical products and there are significant risks involved in the building and managing of a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize cretostimogene or any future product candidates in foreign markets. We are not permitted to market or promote cretostimogene or any future product candidate before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for cretostimogene or any future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of cretostimogene or any future product candidates. Approval procedures may be more onerous than those in the United States and may require that we conduct additional preclinical studies or clinical trials. If we obtain regulatory approval of cretostimogene or any future product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- compliance with export control and import laws and regulations and unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing, and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, public health pandemics or epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to cretostimogene or any future product candidates, which may change from time to time, including the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the timing and success or failure of preclinical studies or clinical trials for cretostimogene or any future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- coverage and reimbursement policies with respect to cretostimogene or any future product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing cretostimogene or any future product candidates, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, in-license, develop, or commercialize additional product candidates;
- the level of demand for any approved products, which may vary significantly and be difficult to predict;
- our ability to commercialize cretostimogene or any future 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;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and amount of any milestone, royalty or other payments payable by us or due to us under any collaboration, licensing or other similar agreement.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, 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.

Our success is dependent on our ability to attract and retain highly qualified management and other clinical and scientific personnel.

Our success depends in part on our continued ability to attract, recruit, retain, manage, and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our clinical trials and preclinical studies, regulatory approvals or the commercialization of cretostimogene or any future product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, employment 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, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may encounter difficulties in managing our growth and expanding our operations successfully, including our recent CFO transition, which could disrupt our operations.

As of December 31, 2023, we had 61 full-time employees. As we continue development and pursue the potential commercialization of cretostimogene or any future product candidates, as well as transition to functioning as a public company, we will need to expand our financial, development, regulatory, manufacturing, information technology, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties and we may not be successful in doing so. Our future financial performance and our ability to develop and commercialize cretostimogene and any future product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

In addition, in January 2024, we appointed Corleen Roche as our Chief Financial Officer succeeding Stephen DiPalma. While we expect Mr. DiPalma to continue to provide consulting services to assist with the transition on a part-time basis, we may experience difficulties associated with timely and successfully executing a smooth transition of the Chief Financial Officer functions.

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 physicians 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 biopharmaceutical companies to comply with the biopharmaceutical 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 biopharmaceutical 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 consulting agreements and 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.

Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize cretostimogene or any future product candidates and may adversely 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 cretostimogene or any future 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (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 established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. 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. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect until 2032, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. 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, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products.

Most recently, 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 (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. 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, although the Medicare drug price negotiation program is currently subject to legal challenges. 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.

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, financial condition, results of operations 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 cretostimogene and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that these existing 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 cretostimogene or any future product candidates, if approved.

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

We face an inherent risk of product liability as a result of the clinical trials of cretostimogene and any future product candidates and will face an even greater risk if we commercialize cretostimogene or any future product candidates, if approved. For example, we may be sued if cretostimogene or any future product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management’s time and our resources;
- substantial monetary awards to trial participants or product recipients;

- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize cretostimogene or any future product candidate; and
- a decline in our stock price.

We currently hold approximately $10 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of cretostimogene or any future product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of cretostimogene or any future product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our insurance policies are expensive and protect us from only some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, business automobile, workers' compensation, products/clinical trial liability, cyber liability, clinical trials, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

We and any of our current or potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we or any of our current or potential future collaborators are successful in commercializing cretostimogene or any future product candidates, the FDA and foreign regulatory authorities would require that we and such collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we or such collaborators become aware of the adverse event as well as the nature of the event. We and any of our current or potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our current or potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

We and our service providers may be subject to a variety of data protection, privacy and security obligations, including laws, regulations, standards and contractual provisions, which could increase compliance costs, and our actual or perceived failure to comply with such laws and obligations could subject us to potentially significant liability, fines or penalties and otherwise harm our business.

We and our service providers maintain and will maintain a large quantity of sensitive information, including confidential business and patient health information, in connection with our clinical trials, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers may be affected by or subject to existing, amended, or new laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, thus creating potentially complex compliance issues for us and our service providers, strategic partners and future customers. The cost of compliance with these laws,

regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws and consumer protection laws, that govern the collection, use, storage, transfer, disclosure, protection and other processing of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data and CROs) that are subject to privacy and security requirements under HIPAA. Consequently, depending on the facts and circumstances, we could be subject to significant penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider, research institution, or CRO that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In addition, certain state laws govern the privacy and security of health-related and other personal information, many of which may differ from each other and from HIPAA, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, gives California residents a number of individual privacy rights related to how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, store, use, transfer, disclose and otherwise process data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and our service providers to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and adversely affect our business, financial condition, results of operations and prospects.

Our information technology systems, or those of any of our service providers, may fail or suffer security incidents and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary and confidential business information and personal information). Our information technology systems and those of our third-party service providers, strategic partners and other contractors

or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication 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 nation-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. In addition, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. 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 incidents 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.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any material system failure, accident or security breach to date, if any such event, whether actual or perceived, were to occur, it could impact our reputation and/or operations, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on a third party to manufacture cretostimogene, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security incident affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our confidential or proprietary data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of cretostimogene or any future product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from incidents experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. 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. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses.

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

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. Any future pandemic or epidemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for cretostimogene or any future product candidates for use in our, our collaborators' or any future collaborators' clinical trials and research and preclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, alter the results of the clinical trial based on participants contracting the disease or otherwise

increasing the number of observed adverse events, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition, results of operations and prospects. Any future pandemic or epidemic disease outbreak could also potentially further affect the business of the FDA, European Medicines Agency or other regulatory authorities, which could result in delays in meetings related to our planned clinical trials, as well have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

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

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. For example, on March 4, 2024, a complaint was filed in the Superior Court of the State of Delaware by ANI Pharmaceuticals, Inc. naming us as defendant, seeking a declaratory judgement that a provision in an assignment and technology transfer agreement between us and ANI (formerly BioSante Pharmaceuticals, Inc.), dated November 15, 2010, obligates us to pay ANI 5% of worldwide net sales of cretostimogene. While we believe the allegations are without merit and intend to vigorously defend this matter, such litigation could result in substantial costs and divert our management's attention from other business concerns, cause us reputational damage, negatively affect our stock price and result in monetary damages and future royalty obligations, if and to the extent cretostimogene receives regulatory approval. An adverse outcome resulting from any legal proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

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

We are exposed to the risk that our employees and independent contractors, including collaborators, principal investigators, CROs, consultants, and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad (iv) laws that require the true, complete and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our or our collaborators' preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines,

disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

We may engage in strategic transactions that could impact our liquidity, increase our expenses, and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships and collaborations, joint ventures, restructurings, divestitures, business combinations, and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our ability to use 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 may never achieve profitability. As of December 31, 2023, we had net operating loss (NOL) carryforwards, which may be available to offset our future taxable income, if any. Our NOL carryforwards and other tax attributes are subject to expiration, review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the Code), our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an "ownership change." For these purposes, an "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. Although we believe there have been one or more ownership changes resulting from past transactions, we have not determined the amount of the cumulative change in our ownership resulting from our initial public offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected.

We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for cretostimogene or any future product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize cretostimogene or any future product candidates may be adversely affected.

We rely, and may in the future rely, upon a combination of patent, trade secrets and trademark protection for cretostimogene and any future product candidates and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property protection in the United States and other countries with respect to cretostimogene and any future product candidates and other proprietary technologies we may develop. We generally seek, and may in the future seek, to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to cretostimogene and any future product candidates and technology, manufacturing processes and methods of use. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications from third parties. Currently we do not have composition of matter patents covering cretostimogene. We will endeavor to seek additional patent protection to cover features of the oncolytic virus and formulations in the future. If we are unable to obtain, maintain, expand, enforce and defend the scope, ownership or control, validity and enforceability of our intellectual property protection, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain, expand, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue or may in-license will issue as patents in any particular jurisdiction, whether the claims of any issued patents will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, whether the patents will be found to be invalid, unenforceable, or not infringed or not owned or controlled by us. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with cretostimogene or any future product candidates or technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or the entity from which we purchased the intellectual property rights to cretostimogene were the first to invent the inventions claimed in any of our owned patents or pending patent applications, or that we or any future licensors were the first to file for patent protection of such other inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such other inventions, our patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued.

Any issued patents may not afford sufficient protection of cretostimogene or any future product candidates or their intended uses against competitors, nor can there be any assurance that the issued patents will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or cretostimogene or any future product candidates. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, information disclosure, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. In the event we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we own or may license in the future covering cretostimogene or any future product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U.S. Patent and Trademark Office (USPTO). Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on cretostimogene or any future product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, ownership, validity, enforceability of our patents and/or other intellectual property. Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect cretostimogene or any future product candidates. Further, if we encounter delays in our development and testing of cretostimogene or any future product candidates, clinical trials or regulatory review and approval of cretostimogene or any future product candidates, the period of time during which we could market cretostimogene or any future product candidates under patent protection may be reduced (i.e., patents protecting such product candidates might expire before or shortly after such product candidates are commercialized). Thus, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our owned and any future in-licensed patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether cretostimogene or any future product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. Furthermore, our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments) to conduct research and clinical trials.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a post-grant proceeding at the USPTO challenging the validity of one or more claims of our patents or patents we may license in the future. Third-party submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on our pending patent application or patent application we may license in the future. A third party may also claim that our patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, interference proceedings or other similar proceedings in the United States and/or foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, and may allow third parties, including generic drug companies, to commercialize cretostimogene or any future product candidates and other proprietary technologies we may develop and compete directly with us.

Moreover, some of our patent rights may in the future be co-owned with third parties. In the United States, each co-owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, enforcing and defending patents on cretostimogene or any future product candidates in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, including limiting patent protection to specifically disclosed embodiments. 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 intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or patents we may license in the future or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property 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 protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a heightened standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our intellectual property and proprietary rights in the United States or other jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and any patents we may license in the future at risk of being invalidated or interpreted narrowly, could put our patent applications and any patent applications we may license in the future at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, including governmental agencies. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geo-political actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement or defense of our issued patents which could impair our competitive intellectual property position.

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

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we may be dependent on any future licensors to take the necessary action to comply with these requirements with respect to any licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. In certain circumstances, we may rely on licensing partners to pay these fees due to the U.S. and non-U.S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We would also be dependent on any future licensors to take the necessary actions to comply with these requirements with respect to any intellectual property we may license in the future.

Public health pandemics (such as the COVID-19 pandemic), geopolitical instability (war and terrorism), natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for cretostimogene and any future product candidates.

Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability 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 us or our licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we or our licensors had made the invention before it was made by such third party. This requires us to be cognizant 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 are the first to either (i) file any patent application related to cretostimogene or any future product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and 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. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. 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. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the U.S. Supreme Court held in *Amgen v. Sanofi (2023)* that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Similarly, changes in patent law 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 or may obtain or license in the future.

In 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and cretostimogene and any future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

Issued patents covering cretostimogene or any future product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any future licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we initiate legal proceedings against a third party to enforce a patent covering cretostimogene or any future product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation

in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading or inconsistent statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, shortening the term of or amendment to our patent rights or any patent rights we may obtain or license in the future in such a way that they no longer cover cretostimogene or any future product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for cretostimogene or any future product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect the competitive position of cretostimogene or any future product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering cretostimogene or any future product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of cretostimogene or any future product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations and prospects will be adversely affected.

If we do not obtain patent term extension and equivalent extensions outside of the United States for cretostimogene or any future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA regulatory approval of cretostimogene or any future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we may license from a third party in the future, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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, consultants, licensees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor, co-inventor or owner of trade secrets. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing cretostimogene or any future product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as ownership of, or the right to use intellectual property that is important to cretostimogene or any future product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for cretostimogene or any future product candidates and proprietary technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. 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. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. 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, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing cretostimogene or any future product candidates. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to cretostimogene or any future product candidates and other proprietary technologies we may develop. 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 our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors 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 these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management.

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.

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 cretostimogene or any future product candidates.

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 or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of cretostimogene or any future product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering cretostimogene or any future product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, 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 patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that cretostimogene or any future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Alternatively, we may incorrectly determine that the Hatch-Waxman Amendments are a defense for a safe harbor to infringement of a patent we consider relevant to the research or clinical development of cretostimogene or any future product candidate. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market cretostimogene or any future product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing cretostimogene or any future product candidates that are held to be infringing. We might, if possible, also be forced to redesign cretostimogene or any future

product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement, misappropriation, or other violations against us or our collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of cretostimogene or any future product candidates.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our therapeutic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our therapeutic programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot guarantee that our therapeutic programs and other proprietary technologies we develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our therapeutic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to cretostimogene or any future product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover cretostimogene or any future product candidates or the use of cretostimogene or any such product candidates.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater

financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and 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. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and 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. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at cretostimogene or any future product candidates.

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

Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent we own or a patent we may license in the future is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. In addition, our patent rights may become involved in inventorship, ownership, priority, enforceability, or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and 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. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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 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 registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In the event that our trademarks are successfully challenged or determined to be infringing, misappropriating or violating other marks, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. 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, which may not survive such proceedings. Moreover, any name we may propose to use with cretostimogene or any future product candidates 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, we 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, misappropriate or otherwise violate 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.

We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors 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, misappropriation, dilution or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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 products that are similar to cretostimogene or any future product candidates or utilize similar technology but that are not covered by the claims of the patents that we own or may license in the future;
- we or our licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our licensors or collaborators might not have been the first to file patent applications covering our or their 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 and future patent applications that we own or may license will not lead to issued patents;
- any issued patent that we own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we or our licensors 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 may fail to identify potential patentable subject matter and/or may fail to file on it;

- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secrets.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

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

The growth of our business may depend in part on our ability to acquire, in-license or use third-party intellectual property and proprietary rights. For example, cretostimogene or any future product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, we may develop combination therapies with our compounds and third-party compounds, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners' interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those 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, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we may collaborate with academic institutions to accelerate our research and development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. Even if we are able to obtain a license, it may be non-exclusive, and our competitors may also receive access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive area, 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 cretostimogene or any future product candidates. More established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding cretostimogene or any future product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business, financial condition, results of operations, and prospects could suffer.

Risks Related to Ownership of Our Common Stock

Prior to our initial public offering, there was no public market for our common stock. An active, liquid and orderly market for our common stock may not develop or be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq.

Prior to our initial public offering, there was no public market for our common stock. Our common stock only recently began trading on the Nasdaq Global Select Market (Nasdaq) and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active market is developed, it may not be sustained. If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business. .

If, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

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

- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- our ability to obtain and maintain regulatory approval of cretostimogene or any future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire, or license cretostimogene or any future product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;

- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors or key personnel;
- intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs, divert our management's attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As of March 25, 2024, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 39.5% of our outstanding common stock. As a result, such persons acting together, have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

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

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their 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.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

In connection with our initial public offering, our directors and executive officers and substantially all of our securityholders entered into lock-up agreements with the representatives pursuant to which they may not, with limited exceptions, through July 22, 2024, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Morgan Stanley & Co. LLC and Goldman Sachs & Co. LLC. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, these shares of common stock will be eligible for sale in the public market, except that shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act.

In addition, as of December 31, 2023, 5,222,283 shares of common stock that are subject to outstanding options under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of 38,413,913 shares of our outstanding common stock, or approximately 57.6% of our total outstanding common stock based on shares outstanding as of March 25, 2024, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting and the 180-day lock-up agreements described above. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer", as defined under the Exchange Act, our annual gross revenue exceeds $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley);
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. 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 allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this

exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

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 our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation also provides 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. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar 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 these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions 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 adversely affect our business and financial condition.

General Risk Factors

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. The increased costs will decrease our net income or increase our net loss, and may require us to reduce expenditures in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements. The impact of these requirements could also make it more difficult for us to attract and retain

qualified persons to serve on our board of directors, our board committees or as executive officers. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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. We could face criminal liability and other serious consequences for violations, which could 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, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, 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, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective.

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.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time-consuming or costly.

We and any of our third-party manufacturers or suppliers and our current or any future collaborators may use biological materials, potent chemical agents, and hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, neither we or our third-party manufacturers and suppliers can eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury at our, our manufacturers' or our suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance

for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

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

Our operations and the operations of our manufacturers, suppliers, collaborators, CROs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics (including, for example, the COVID-19 pandemic) and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers or suppliers to produce cretostimogene or any future product candidates and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of cretostimogene or any future product candidates. Our ability to obtain clinical or, if approved, commercial, supplies of cretostimogene or any future product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. In addition, our corporate headquarters is located in Irvine, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. 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 and adverse developments with respect to financial institutions and associated liquidity risk 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. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts between Russia and Ukraine and in the Middle East, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. In addition, in 2023 the closures of financial institutions and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants 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, limit, reduce or abandon product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows, or adversely impact the value of an investment in our common stock.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the second annual report following the completion of our initial public offering. When we lose our status as an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" with less than $100.0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market 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.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

None

Item 1C. Cybersecurity.

Cybersecurity Risk Management Strategy

We have developed our cybersecurity risk management program ("cybersecurity framework"), including a cybersecurity incident response plan, based on the National Institute of Standards and Technology Cybersecurity Framework's (NIST CSF) principles: Identify, Protect, Detect, Respond, and Recover, and our cybersecurity framework is intended to address current vulnerabilities and anticipate future cybersecurity threats and risks to our cyber ecosystem. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

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

Our cybersecurity risk management program includes:

- assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT environment;
- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response process that includes procedures for responding to cybersecurity incidents; and
- a risk evaluation of the service providers, suppliers, and vendors of critical systems during contracting.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. There can be no assurance, however, that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information. For more information, see the section titled "Risk Factors—Risks Related to Our Business Operations and Industry—*Our information technology systems, or those of any of our service providers, may fail or suffer security incidents and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business."*

Cybersecurity Governance

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

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

The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. The Audit Committee members receive presentations on cybersecurity topics from our Director of Information Technology, or external experts as part of the Audit Committee's continuing education on topics that impact public companies.

Our management team, including our Director of Information Technology, has a combined 35 years of risk management experience and is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. The experience of our management team encompasses leadership, development, and support of cybersecurity strategies, along with the implementation of policies and procedures. Furthermore, they possess a track record of proactively monitoring cybersecurity threats and promptly responding to and remediating cyber attacks. Their adeptness in executing security controls has consistently yielded clean audit observations, showcasing their effectiveness in safeguarding against potential risks.

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

Item 2. Properties.

Our principal executive offices are located in Irvine, California and consist of approximately 1,249 square feet of office space leased until August 2026. We also lease additional office space in Emeryville, California under a lease which ends in August 2025. We believe that our existing facilities will be adequate for the foreseeable future and that suitable additional or substitute space will be available as and when needed.

Item 3. Legal Proceedings.

From time to time, we may be subject to other legal proceedings. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

On March 4, 2024, a complaint was filed against us in the Superior Court of the State of Delaware by ANI Pharmaceuticals, Inc. seeking a declaratory judgement that an assignment and technology transfer agreement between us and ANI, dated November 15, 2010, obligates us to pay ANI a royalty on certain "net sales" of cretostimogene. We dispute the allegations and intend to vigorously defend this matter.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol "CGON" since our initial public offering on January 25, 2024, which was completed at a price to the public of $19.00 per share. Prior to our initial public offering, there was no public market for our common stock.

Holders of Common Stock

As of January 31, 2024, there were 66,636,192 shares of our common stock outstanding held by approximately 111 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of director after considering our financial condition, results of operations, current and anticipated capital requirements, business prospects and other factors our board of directors deems relevant, and subject to applicable laws and the restrictions contained in any future financing instruments.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this Annual Report for information about our equity compensation plans which is incorporated by reference herein.

Performance Graph

Not applicable.

Unregistered Sales of Equity Securities

a) Issuances of Securities

In July 2023, we entered into a Series F preferred stock purchase agreement, pursuant to which we issued and sold in July 2023 an aggregate of 81,587,937 shares of Series F redeemable convertible preferred stock at a purchase price of $1.2872 per share, for aggregate consideration of approximately $105 million.

No underwriters were involved in the foregoing issuances of securities. These securities described in this section (a) were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All holders of securities described above represented to us in connection with their purchase or issuance that they were accredited investors and were acquiring the securities for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The holders received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

b) Grants of Stock Options

During 2023, we granted to certain of our directors, employees and consultants (in connection with services provided to us by such persons) options to purchase 3,346,939 shares of our common stock with a weighted average exercise price of $5.78 under the CG Oncology, Inc. 2022 Incentive Award Plan, as amended.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information. On January 26, 2024, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 5 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

Use of Proceeds

On January 24, 2024, our registration statement on Form S-1 (File No. 333-276350) was declared effective by the SEC for our initial public offering. At the closing of our initial public offering on January 29, 2024, we sold 23,000,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 3,000,000 additional shares, at an initial public offering price of $19.00 per share and received gross proceeds of $437.0 million, which resulted in net proceeds to us of approximately $400.4 million, after deducting underwriting discounts and commissions of approximately $30.6 million and offering-related transaction costs of approximately $6.0 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. Morgan Stanley & Co. LLC, Goldman Sachs & Co. LLC and Cantor Fitzgerald & Co. acted as joint book-running managers for the initial public offering.

Upon receipt, the net proceeds from the initial public offering were held in cash and cash equivalents and marketable securities. There has been no material change in the planned use of proceeds from our initial public offering from that described in the Annual Report for the initial public offering.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward Looking Statements and Market Data." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk factors" in this Annual Report.

Overview

We are a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients afflicted with bladder cancer. Our product candidate, cretostimogene, is initially in clinical development for the treatment of patients with high-risk NMIBC who are unresponsive to BCG therapy, the current standard-of-care for high-risk NMIBC. There is significant unmet need for treatments in these patients given the limitations of currently approved therapies and patient reluctance to undergo radical cystectomy, or the complete removal of the bladder. We are evaluating the safety and efficacy of cretostimogene as monotherapy in BOND-003, our ongoing Phase 3 clinical trial in high-risk BCG-unresponsive NMIBC patients. We have completed enrollment for this trial, reported interim data in November 2023 and expect to report topline data by the end of 2024. If successful, we believe that this trial could serve as the basis for a BLA submission to the U.S. FDA. We are also evaluating the use of cretostimogene when administered to this same patient population in combination with FDA-approved pembrolizumab in CORE-001, our ongoing Phase 2 clinical trial. Moreover, we intend to assess the safety and efficacy of cretostimogene in treating a range of other bladder cancer indications as an alternative to BCG therapy and in patients who are not categorized as BCG-unresponsive, including our second Phase 3 clinical trial, PIVOT-006, evaluating adjuvant cretostimogene in intermediate-risk NMIBC patients following TURBT. We believe cretostimogene, if approved, has the potential to serve as first-line therapy, thereby alleviating the current need to prioritize treatment recipients and ration administration of BCG given its significant market shortage.

Since our inception in 2010, we have focused substantially all of our resources on organizing and staffing our company, business planning, raising capital, establishing and maintaining our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of cretostimogene, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales.

We have incurred significant operating losses and negative cash flows from operations since our inception. Our net losses were $48.6 million and $35.4 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $129.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and, to a lesser extent, from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses in the foreseeable future, and we anticipate these losses will increase substantially as we as we continue our development of, seek regulatory approval for, and potentially commercialize cretostimogene and potentially seek to discover and develop additional product candidates, utilize third parties to manufacture cretostimogene, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company. If we obtain regulatory approval for cretostimogene, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing and distribution. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we do not become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce or terminate our operations.

To date, we have primarily funded our operations with proceeds from the sale of shares of our redeemable convertible preferred stock and previously outstanding term debt. Through December 31, 2023, we have received aggregate gross proceeds of approximately $307.9 million from the sale of shares of our redeemable convertible

preferred stock. In addition, through December 31, 2023, we have recognized $25.0 million in research and collaboration revenue pursuant to our license and collaboration agreements. As of December 31, 2023, we had cash, cash equivalents and marketable securities of $187.7 million. In July 2023, we received net proceeds of $104.6 million from the sale of shares of our Series F redeemable convertible preferred stock. Our ability to generate any product revenue and, in particular, our ability to generate product revenue sufficient to achieve profitability, will depend on the successful development and eventual commercialization of cretostimogene and any future product candidates.

Based on our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our projected operating expenses and capital expenditure requirements through 2027. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for cretostimogene or any future product candidates, which we expect will take a number of years and may never occur. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements or arrangements as, and when needed, we may delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or even cease operations.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of cretostimogene for clinical testing, as well as for commercial manufacture if we obtain marketing approval. In addition, we rely on third parties to package, label, store, and distribute cretostimogene, and we intend to rely on third parties for our commercial products if marketing approval is obtained. We believe that this strategy allows us to maintain a more efficient infrastructure by eliminating the need for us to invest in our own manufacturing facilities, equipment, and personnel while also enabling us to focus our expertise and resources on the development of cretostimogene.

In January 2024, we completed our initial public offering of 23,000,000 common shares at a price of $19.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 3,000,000 shares of common stock. We received net proceeds of $400.4 million, after deducting discounts and commissions and estimated offering expenses. In addition, as a result of our initial public offering, our convertible preferred stock converted into common stock concurrently with the initial public offering.

License and Collaboration Agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see the section titled “Business—License and Collaboration Agreements”.

Lepu License Agreement

In March 2019, we entered into a development and license agreement (the Lepu License Agreement) with Lepu, under which we granted an exclusive license to Lepu to develop, manufacture and commercialize cretostimogene and/or DDM to treat and/or prevent cancer in the Lepu Territory. Lepu paid to us a one-time upfront payment of $4.5 million and is obligated to make regulatory milestone payments of up to $2.5 million and commercial milestone payments of up to $57.5 million. We are entitled to receive a high single-digit royalty on net sales of cretostimogene and/or DDM sold in the Lepu Territory, subject to a specified reduction. During the years ended December 31, 2023 and 2022, less than $0.1 million and zero revenue, respectively, was recorded related to the Lepu License Agreement.

Kissei License Agreement

In March 2020, and as amended September 2022, we entered into a license and collaboration agreement (the Kissei License Agreement) with Kissei, under which we granted to Kissei an exclusive license to certain intellectual property rights in Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, Nepal, Pakistan, Palau, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam (the Kissei Territory), for Kissei to develop and commercialize, but not manufacture, cretostimogene in combination with DDM (the Licensed Product) for all uses in oncology. Kissei paid to us a one-time upfront payment of $10.0 million under the agreement. Kissei is obligated to development milestone payments of up to $33.0 million and commercial milestone payments of up to $67.0 million. We have also agreed to pay Kissei a royalty on net sales of Licensed Product outside the Kissei Territory and outside the Lepu Territory, including on any U.S. sales, in a low-single digit percentage, subject to certain capped reductions. We are entitled to receive a royalty on net sales of Licensed Product in the Kissei Territory in the mid-twenties percentage, subject to certain capped reductions and offset rights. We are obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from us. During the years ended December 31, 2023 and 2022, we recorded $0.2 million and $0.2 million, respectively in development income related to the Kissei License Agreement.

Components of Our Results of Operations

Revenue

Through December 31, 2023, we have recognized $25.0 million in research and collaboration revenue through our license and collaboration agreements. We have not generated any revenue from the sale of products, however, and do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. If our or our collaborators' development efforts for cretostimogene and any future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales, payments from existing or potential future collaboration or license agreements with third parties, or any combination thereof.

Operating Expenses

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

Research and Development Expenses

Research and development (R&D) expenses consist primarily of external and internal costs incurred in performing clinical and preclinical development activities.

Our R&D expenses consist of:

- external costs incurred under agreements with CROs, contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies; and
- internal costs, including R&D personnel-related expenses such as salaries, stock-based compensation and benefits, as well as allocated facilities costs and dues and subscriptions.

We expense R&D costs as incurred. We currently only have one product candidate, cretostimogene. Therefore, since our inception, substantially all of our R&D costs were related to the development of cretostimogene. We track R&D expenses on an aggregate basis and not on an indication-by-indication or treatment setting-by-treatment setting basis.

Although R&D activities are central to our business model, the successful development of cretostimogene and any future product candidates is highly uncertain. There are numerous factors associated with the successful development of any product candidate such as cretostimogene, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. In addition, future regulatory factors beyond our control may impact our clinical development programs. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages

of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our R&D expenses will increase substantially in connection with our ongoing and planned clinical and preclinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of cretostimogene and any future product candidates. Our future R&D expenses may vary significantly based on a wide variety of factors such as:

- the number and scope, rate of progress, expense and results of our clinical trials and preclinical studies of cretostimogene and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing cretostimogene and any future product candidates;
- the costs, if any, of obtaining third-party drugs for use in our combination trials;
- the extent of changes in government regulation and regulatory guidance;
- the efficacy and safety profile of cretostimogene and any future product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities; and
- the extent to which we establish additional collaboration, license, or other arrangements.

A change in the outcome of any of these variables with respect to the development of cretostimogene or any future product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses such as salaries, stock- based compensation and benefits, for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters and professional fees paid for accounting, auditing, consulting and tax services, as well as facilities-related costs not otherwise included in R&D expenses and other costs such as insurance costs and travel expenses.

We anticipate our general and administrative expenses will increase substantially in the future as we expand our operations, including increasing our headcount to support our continued R&D activities and preparing for potential commercialization of cretostimogene. We also anticipate we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations expenses associated with operating as a public company.

Other (Expense) Income, Net

Interest (Expense) Income, Net

Interest income, net, consists of interest income related to interest earned on our invested cash and cash equivalents and marketable securities balances and expenses related to our previously outstanding term debt. We expect our interest income will increase as we invest the cash received from the net proceeds from our initial public offering.

Other (Expense) Income

Other (expense) income consists of miscellaneous items, such as debt extinguishment due to early payoff of loan and other items not related to our core operations.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

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

	Year Ended December 31,		
	2023	2022	Change
Revenue:			
Research and collaboration revenue	$ 204	$ 191	$ 13
Operating expenses:			
Research and development	45,752	29,029	(16,723)
General and administrative	9,901	6,408	(3,493)
Total operating expenses	55,653	35,437	(20,216)
Loss from operations	(55,449)	(35,246)	(20,203)
Other income (expense), net:			
Interest income (expense), net	6,904	(1)	6,905
Other (expense), net	(62)	(196)	134
Total other income (expense), net	6,842	(197)	7,039
Net loss and comprehensive loss	$ (48,607)	$ (35,443)	$ (13,164)

Research and Collaboration Revenue

Research and collaboration revenue was $0.2 million for the year ended December 31, 2023 compared to $0.2 million for the year ended December 31, 2022. During the years ended December 31, 2023 and 2022, we recorded $0.2 million and less than $0.1 million, respectively, in development income related to the Kissei License Agreement and the Lepu License Agreement.

Research and Development Expenses

The following table summarizes our R&D expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	2022	Change
External clinical trial expenses	$ 31,543	$ 19,314	$ 12,229
Personnel-related expenses	12,942	8,966	3,976
Facilities-related fees and other expenses	1,267	749	518
Total research and development expenses	$ 45,752	$ 29,029	$ 16,723

R&D expenses were $45.8 million for the year ended December 31, 2023 compared to $29.0 million for the year ended December 31, 2022. The increase of $16.7 million in R&D expenses for the year ended December 31, 2023 was primarily due to an increase of $12.2 million in clinical trial expenses related to higher CRO fees as patient enrollment increased and higher CMC and consultant and other third party expenses, an increase of $4.0 million in personnel-related expenses due to increased headcount for R&D, and higher facilities-related, fees and other related costs of $0.5 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2023	2022	Change
Personnel-related expenses	$ 5,542	$ 3,310	$ 2,232
Professional and consultant fees	3,170	2,478	692
Facilities-related fees and other expenses	1,189	620	569
Total general and administrative expenses	$ 9,901	$ 6,408	$ 3,493

General and administrative expenses were $9.9 million for the year ended December 31, 2023 compared to $6.4 million for the year ended December 31, 2022. The increase of $3.5 million in general and administrative expenses for the year ended December 31, 2022 was primarily due to an increase in personnel-related expenses of $2.2 million due to increased headcount, increased professional consulting fees related to legal fees, accounting and consulting fees of $0.7 million and higher facilities-related, travel and marketing-related costs of $0.6 million.

Other Income (Expense), Net

Other income (expense), net, for the year ended December 31, 2023 was a net income of $6.8 million compared to a net expense of $0.2 million for the year ended December 31, 2022. For the year ended December 31, 2023, interest income, net and other (expense) income, net primarily consisted of $6.9 million in interest income related to higher marketable securities balances as a result of net proceeds from our Series E and Series F redeemable convertible preferred stock financings in 2023 and 2022, respectively. This was partially offset by debt extinguishment of $0.1 million for early payoff of term loan. For the year ended December 31, 2022, interest expense, net and other (expense) income, net consisted of term loan interest expense, the final payment accretion and related amortization of $1.8 million, offset by interest income of $1.6 million related to marketable securities balances during the year.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We expect to incur significant expenses and operating losses in the foreseeable future as we advance the clinical development of cretostimogene and any future product candidates. To date, we have primarily funded our operations with proceeds from the sale of shares of our redeemable convertible

preferred stock and previously outstanding term debt. Through December 31, 2023, we have received aggregate gross proceeds of $307.9 million from the sale of shares of our redeemable convertible preferred stock. In addition, through December 31, 2023, we have recognized $25.0 million in research and collaboration revenue through our license and collaboration agreements. As of December 31, 2023, we had cash, cash equivalents and marketable securities of $187.7 million. In July 2023, we received net proceeds of $104.6 million from the sale of shares of our Series F redeemable convertible preferred stock. On January 29, 2024, we closed our initial public offering of common stock for aggregate net proceeds of $400.4 million, after deducting discounts and commissions and estimated offering expenses.

In January 2021, we entered into a loan agreement with Silicon Valley Bank for a term loan in three tranches. As of December 31, 2022, we had drawn down $15.0 million in aggregate principal amount under the loan agreement. As of December 31, 2023, we repaid all outstanding principal and accrued and unpaid interest under the loan agreement. See Note 11 to our financial statements included elsewhere in this Annual Report for additional information.

Effects of Inflation

Inflation could affect us by increasing our cost of labor and R&D costs. We do not believe inflation has had a material effect on our business, financial condition or results of operations, or on our financial statements included elsewhere in this Annual Report.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue our development of, seek regulatory approval for, and potentially commercialize cretostimogene and potentially seek to discover and develop additional product candidates, conduct our ongoing and planned clinical trials and preclinical studies, continue our R&D activities, utilize third parties to manufacture cretostimogene, hire additional personnel, expand and protect our intellectual property, and incur additional costs associated with being a public company

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses, and prepaid expenses. The timing and amount of our funding requirements will depend on many factors, including:

- the initiation, type, number, scope, progress, expansions, results, costs and timing of clinical trials and preclinical studies of cretostimogene and any future product candidates we may choose to pursue, including the costs of modification to clinical development plans based on feedback that we may receive from regulatory authorities and any third-party products used as combination agents in our clinical trials
- the costs, timing and outcome of regulatory meetings and reviews of cretostimogene or any future product candidates, including requirements of regulatory authorities in any additional jurisdictions in which we may seek approval for cretostimogene and any future product candidates;
- the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting;
- the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, CMC quality and commercial personnel;
- the timing and payment of milestone, royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;
- the costs and timing of establishing or securing sales and marketing capabilities if cretostimogene or any future product candidate is approved;

- our ability to achieve sufficient market acceptance, coverage, and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products;
- our ability and strategic decision to develop future product candidates other than cretostimogene, and the timing of such development, if any;
- patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Based upon our current operating plan, we estimate that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our projected operating expenses and capital expenditure requirements through 2027. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. In addition, we could utilize our available capital resources sooner than we expect.

We have no other committed sources of capital. Until such time, if ever, we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent 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 common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions, engaging in acquisition, merger or collaboration transactions, selling or licensing our assets, making capital expenditures, redeeming our stock, making certain investments or declaring dividends. If we raise additional funds through collaborations or license agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise product candidates that we would otherwise prefer to develop and market ourselves, or even cease operations.

Material Cash Requirements for Known Contractual and Other Obligations

Leases

We have entered into various non-cancelable operating leases for our corporate office. The leases have varying terms expiring between 2025 and 2026. See Note 5 to our financial statements included elsewhere in this Annual Report for further details.

Research and Development Costs

We are continuing to invest in our cretostimogene clinical trials and have entered into contractual obligations with each clinical trial site. Each contract shall continue until the completion of the trial at that site. Our clinical trial costs are dependent on, among other things, the size, number and length of our clinical trials.

Other Capital Requirements and Additional Royalty Obligations

We enter into agreements in the normal course of business with various vendors, which are generally cancellable upon notice. Payments due upon cancellation typically consist only of payments for services provided or expenses incurred, including non-cancellable obligations of service providers, up to the date of cancellation.

In addition to our obligation to make potential royalty payments under the Kissei License Agreement discussed above, we are also obligated to pay royalties and milestone payments to the initial supplier of a certain cell line we use to manufacture cretostimogene, in an amount less than 1% on the net sales of cretostimogene, worldwide. These royalty obligations last for as long as we use the certain cell line to manufacture cretostimogene. The timing of when our royalty payments will actually be made is uncertain as the payments are contingent upon future activities, including the successful development, regulatory approval and commercialization of cretostimogene.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (45,679)	$ (29,804)
Net cash used in investing activities	(121,195)	(55,352)
Net cash provided by financing activities	86,997	119,692
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (79,877)	$ 34,536

Operating Activities

During the year ended December 31, 2023, operating activities used $45.7 million of cash, primarily resulting from our net loss of $48.6 million, including the non-cash charges of $0.5 million, which consists of stock-based compensation expense, amortization associated with the term loan final payoff and success fees, offset by the accretion of the discount on short-term investments and net cash used in changes in our operating assets and liabilities of $3.4 million.

During the year ended December 31, 2022, operating activities used $29.8 million of cash, primarily resulting from our net loss of $35.4 million, partially offset by non-cash charges of $1.2 million, including stock-based compensation expense and amortization associated with the term loan final payoff and success fees, and net cash used in changes in our operating assets and liabilities of $4.4 million.

Investing Activities

During the year ended December 31, 2023, net cash used in investing activities was $121.2 million, primarily due to purchases of marketable securities and proceeds from sales and maturities of short-term investments.

During the year ended December 31, 2022, net cash used in investing activities was $55.4 million, primarily due to purchases of marketable securities.

Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities was $87.0 million, consisting primarily of net proceeds from the issuance of Series F redeemable convertible preferred stock of $104.6 million and the exercise of common stock options of $2.1 million offset by the payment of the term loan of $16.3 million and the deferred offering costs of $3.4 million.

During the year ended December 31, 2022, net cash provided by financing activities was $119.7 million, consisting of net proceeds from the issuance of Series E redeemable convertible preferred stock of $119.5 million and the exercise of common stock options of $0.2 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our financial statements included elsewhere in this Annual Report, we believe the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

R&D Expenses and Related Prepaid and Accrued Expenses

As part of the process of preparing our financial statements, we are required to estimate our R&D expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our R&D expenses as of each balance sheet date based on facts and circumstances known to us at that time. The significant estimates in our R&D expenses include the costs incurred for services performed by our vendors in connection with services for which we have not yet been invoiced. We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct R&D on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows.

There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the R&D expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

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

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Standards

A description of recently issued accounting standards that may potentially impact our financial position, results of operations and cash flows is included in Note 2 to our financial statements included elsewhere in this Annual Report.

Emerging Growth Company Status and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards. We have elected to avail ourselves of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to opt out of such extended transition period or (ii) no longer qualify as an emerging growth company. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies. We will continue to remain an emerging growth company until the earliest of the following: (1) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (2) the last day of the fiscal year in which our total annual gross revenue is equal to or more than $1.235 billion; (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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 our voting and non-voting common stock held by non-affiliates is less than 250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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

Interest Rate Risk

Our cash, cash equivalents, and marketable securities consist of cash held in readily available checking and money market accounts, as well as short-term debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short- term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations.

Under our investment policy, we invest in highly rated securities, issued by the U.S. government or liquid money market funds. We do not invest in financial instruments for trading or speculative purposes, nor do we use leveraged financial instruments. A hypothetical 10% change in interest rates would not have a material impact on the value of our cash, cash equivalents, marketable securities. and cash flows.

Foreign Currency Exchange Risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. As we continue to develop our business, our results of operations and cash flows will likely be more affected by fluctuations in foreign currency exchange rates, including the Euro and other currencies, which could adversely affect our results of operations. All of our employees and operations are currently located in the United States and our expenses are generally denominated in U.S. dollar. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material impact on our financial statements included elsewhere in this Annual Report.

Effects of Inflation

Inflation could affect us by increasing our cost of labor and R&D costs. We do not believe inflation has had a material effect on our business, financial condition or results of operations, or on our financial statements included elsewhere in this Annual Report.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the report of our independent registered public accounting firm, are included in this Annual Report on Form 10-K beginning on page F-1.

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

None.

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and our principal financial officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Annual Report. Based on such evaluation, our principal executive officer and our principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the year ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the three

months ended December 31, 2023, none of our officers or directors adopted or terminated any such trading arrangements.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Management and Board of Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of March 25, 2024.

Name	Age	Position(s)
Executive Officers and Employee Directors		
Arthur Kuan	33	Chairman and Chief Executive Officer
Ambaw Bellete	53	President and Chief Operating Officer
Corleen Roche	58	Chief Financial Officer and Secretary
Vijay Kasturi, M.D.	56	Chief Medical Officer
Non-Employee Directors		
Susan Graf[2][3]	51	Director
Brian Liu, M.D.[1][2]	35	Director
James J. Mulé, IPh.D.	71	Director
Leonard Post, Ph.D.[1][3]	71	Director
Hong Fang "Simone" Song[1][2]	58	Director
Victor Tong, Jr.[3]	40	Director

(1) Member of the compensation committee.
(2) Member of the audit committee.
(3) Member of the nominating and corporate governance committee.

Executive Officers

Arthur Kuan has served as our Chief Executive Officer and as a member of our board of directors since our inception in 2017, and as Chairman since December 2023. Mr. Kuan is also a founding member of Ally Bridge Group, a global healthcare-focused investment platform, and serves on the IP Commercialization Strategy Committee at Moffit Cancer Center. Previously, Mr. Kuan was a member of Themes Investment Partners, a Private Equity fund based in Hong Kong, where he played a central role in coordinating cross-border technology transfer and regulatory submissions for portfolio companies. Mr. Kuan began his career in an operational role at Dinova Capital, a Shanghai-based, medical technology incubator fund, evaluating medical device investment opportunities. Mr. Kuan received his M.S. in Biotechnology from the Johns Hopkins University and his B.A. in Biology from the University of Pennsylvania. Mr. Kuan's knowledge of our business and experience investing in a number of biopharmaceutical companies contributed to our board of directors' conclusion that he should serve as a director of our company.

Ambaw Bellete has served as our President and Chief Operating Officer since July 2023. Previously, Mr. Bellete served as Chief Executive Officer of Lion Healthcare Strategies, a strategic advisory firm, from April 2021 to August 2023, and Chief Operating Officer of FerGene, a gene therapy company dedicated to revolutionizing the treatment of bladder cancer, from March 2020 to March 2021. Prior to FerGene, Mr. Bellete served as the president of Photocure, a company focused on developing and commercializing pharmaceutical products based on photodynamic technology to treat bladder cancer, and also held several global leadership positions with biopharma, biotech and medical device companies, including President of Medical Compression Systems from January 2012 to July 2019. Mr. Bellete started his biopharma career at the Upjohn Company (now Pfizer) and then Sanofi, where he held diverse leadership roles in business development, managed care, marketing and sales positions in specialty, oncology and urology. Mr. Bellete currently serves on the board of directors The Axiom REACH Foundation and OncoSTING. Mr. Bellete holds a B.S. in Biology and Chemistry from Murray State University.

Corleen Roche has served as our Chief Financial Officer and Secretary since January 2024. Previously, Ms. Roche served as the Chief Financial Officer of Immunome, Inc., a publicly-traded biotechnology company, from April 2021 to January 2024. Prior to Immunome, Ms. Roche served as the Chief Financial Officer, U.S. of Biogen Inc. from 2019 until April 2021, and served as the Chief Financial Officer U.S. Biopharma for Sandoz, a division of Novartis, from 2015 to 2019. Ms. Roche began her career at PricewaterhouseCoopers and has served as Chief Financial Officer

at other companies including IoGenetics, Inc. and the Global Vaccines business unit at Wyeth Pharmaceuticals. Ms. Roche holds a B.A. in Accountancy from Villanova University.

Vijay Kasturi has served as our Chief Medical Officer since September 2023. Previously, Dr. Kasturi was Vice President of Clinical Development and Medical Affairs of AVEO Pharmaceuticals, a cancer therapeutics company, from April 2021 to August 2023. Prior to AVEO Pharmaceuticals, Dr. Kasturi was Senior Vice President of Scientific Affairs at FerGene from March 2020 to March 2021. Prior to FerGene, Dr. Kasturi was head of U.S. Medical Affairs, Oncology for EMD Serono, a pharmaceutical company focused on reproductive health, multiple sclerosis and cancer, from November 2015 to March 2020, where he had responsibility for developing global and regional strategies that brought new therapies to patients in immunology, hematology and oncology. Earlier in his career, Dr. Kasturi treated patients with cancer and served as an assistant professor of medicine, Division of Hematology-Oncology at the University of Massachusetts Medical School and as the program leader for genitourinary oncology at UMass Memorial Cancer Center. Dr. Kasturi trained in Hematology-Oncology at the National Cancer Institute (NCI) and worked as an investigator and physician at the NCI and Dartmouth Hitchcock Medical Center. Dr. Kasturi holds an M.D. from Rush Medical College of Rush University and a B.S. in Biology from University of Illinois, Chicago.

Non-Employee Directors

Susan Graf has served as a member of our board of directors since November 2023. Ms. Graf is currently a Senior Advisor and Entrepreneur in Residence at Locust Walk Partners, LLC, a global life science transaction firm. Ms. Graf previously served as Chief Executive Officer of biotechnology company Akamara Therapeutics from August 2019 to May 2021. Prior to Akamara Therapeutics, Ms. Graf was Chief Business Officer and Principal Financial Officer at Epizyme, a biopharmaceutical company, from April 2016 to September 2018. Prior to Epizyme, Ms. Graf held the position of Vice President, Corporate Development and Strategy for NPS Pharma before it was acquired by Shire in 2015. Earlier in her career, Ms. Graf spent nearly 18 years at Roche in a number of leadership and executive positions. Ms. Graf currently chairs the board of directors and audit committee of Finch Therapeutics, a publicly-traded microbiome therapeutics company and serves on the board of directors of Kaléo, a privately held pharmaceutical company. Ms. Graf has an M.B.A. from the Stern School of Business at New York University and a B.Pharm. from Purdue University. Ms. Graf's extensive experience in the life sciences industry and her financial expertise contributed to our board of directors' conclusion that she should serve as a director of our company.

Brian Liu, M.D. has served as a member of our board of directors since September 2022. Dr. Liu is a Managing Director at Longitude Capital, a healthcare venture capital firm, where he has been employed since 2018. Prior to joining Longitude Capital, Dr. Liu was an Engagement Manager in the pharmaceuticals practice of McKinsey & Company from January 2016 to July 2018. Dr. Liu currently serves on the board of directors of Lassen Therapeutics and as a board observer at Quanta Therapeutics., Rivus Pharmaceuticals and Zenas BioPharma. Dr. Liu previously served as a board observer at Endeavor Biomedicines, Inflazome (acquired by Roche Holding), Dascena Lab, Talaris Therapeutics, and Vera Therapeutics. Dr. Liu holds an M.D. from Stanford School of Medicine and a B.S. in Biomedical Engineering from Johns Hopkins University. Dr. Liu's investment experience in the pharmaceutical industry and prior board experience contributed to our board of directors' conclusion that he should serve as a director of our company.

James J. Mulé, IPh.D. has served as a member of our board of directors since 2018. Dr. Mulé has served as Associate Center Director for Translational Science and the Michael McGillicuddy (U.S. Senator Connie Mack (ret.) & Family) Endowed Chair for Melanoma Research and Treatment since 2003 and is the Associate Center Director of the Moffitt Cancer Center, Tampa, Florida, where he has served as a Director since 2003. Since 1993, Dr. Mulé has served multiple tenures as a special government employee to the FDA at the Center for Drug Evaluation and Research and at the Center for Biologics Evaluation and Research and to the National Cancer Institute (NCI). Dr. Mulé also served on the board of directors of publicly-traded company Fulgent Genetics from 2016 to 2020. Dr. Mulé serves on the advisory boards of numerous biotechnology companies, pharmaceutical companies, NCI-designated cancer centers and investment funds, including Buffett Cancer Center, Omaha; Masonic Cancer Center, Minneapolis; Affyimmune Therapeutics; Aleta Biotherapeutics; OncoPep; Turnstone Biologics; UbiVac; Vault Pharma; Vycellix; and Noble Life Science Partners. Dr. Mulé holds an Interdisciplinary Ph.D. in Tumor Immunology, Immunocytology, and Immunopathology from the University of Washington and the Fred Hutchinson Cancer Research Center, Seattle, Washington, a M.S. in Cellular Immunology from the University of Washington School of Medicine and a B.A. from New Jersey City University. Dr. Mulé received his formal postgraduate training at the Surgery Branch, Division of

Cancer Treatment, NCI, National Institutes of Health (NIH), Bethesda, Maryland. Dr. Mulé has held tenured senior positions at the NCI/NIH and the University of Michigan, Ann Arbor. Dr. Mulé's extensive regulatory, basic, translational and clinical research as well as administration leadership experience in both non-profit and for-profit entities and the biopharmaceutical industry contributed to our board of directors' conclusion that he should serve as a director of our company.

Leonard Post, Ph.D. has served as a member of our board of directors since 2018. Dr. Post has over three decades of pharmaceutical R&D experience. From 2016 to 2024, Dr. Post has served as Chief Scientific Officer of Vivace Therapeutics, an oncology company working on small molecules targeting the hippo pathway, and also was Chief Scientific Officer of its sister company Virtuoso Therapeutics, a company working on bispecific antibodies for oncology. He is currently an advisor for both companies. From February 2010 until June 2016, Dr. Post worked at BioMarin, in various positions including Chief Scientific Officer. During that time, he oversaw the initiation of BioMarin's first gene therapy project for hemophilia A. Prior to that, Dr. Post served as Chief Scientific Officer of LEAD Therapeutics, Senior Vice President of Research & Development at Onyx Pharmaceuticals, and Vice President of Discovery Research at Parke-Davis Pharmaceuticals. Dr. Post is also currently an advisor to Canaan Partners. Mr. Post currently serves on the board of directors of uniQure, a publicly-traded biopharmaceutical company, and several privately-held biopharmaceutical companies. Dr. Post also previously served on the board of directors of publicly-traded genetic diagnostics company Fulgent Genetics from August 2022 to October 2022. Dr. Post is a virologist by training and did early work on engineering of herpes simplex virus as a postdoctoral fellow. Dr. Post has a B.S. in Chemistry from the University of Michigan, and a Ph.D. in Biochemistry from the University of Wisconsin. Dr. Post's extensive experience in the biotechnology industry, and specifically in oncolytic viruses, contributed to our board of directors' conclusion that he should serve as a director of our company.

Simone Song has served as a member of our board of directors since November 2015. Ms. Song is the Founder and has been a Senior Partner of ORI Capital Limited, a venture capital firm, since July 2015. Prior to ORI Capital, Ms. Song served as the Head of Healthcare Investment Banking for Greater China for Goldman Sachs. Prior to Goldman Sachs, Ms. Song was a Managing Director of Cowen, a member of the advisory board of AXA Investment Managers, a global investment management firm, and an executive board advisor to AXA Asia Pacific Holdings Limited. Ms. Hong holds a B.A. in Economics from Fudan University and an M.A. in Economics from Claremont Graduate School. Ms. Song's extensive experience in the healthcare sector contributed to our board of directors' conclusion that she should serve as a director of our company.

Victor Tong, Jr. has served as a member of our board of directors since July 2023. Mr. Tong is a Managing Director at Decheng Capital (Decheng), an investment firm, where he has worked since its inception in 2012 and focuses on investments in biotechnology and medical technology companies in China and the United States. Before joining Decheng, Mr. Tong was a Principal at Bay City Capital, a life sciences investment firm, and a member of the healthcare investment banking division at Morgan Stanley. Mr. Tong serves on the board of directors of multiple privately held biotechnology and biopharmaceutical companies including Cellares Corp., EpimAb Biotherapeutics, Harton Therapeutics, Hummingbird Bioscience, LevitasBio, Nalu Medical, Take2, and Watchmaker Genomics. Mr. Tong holds a B.A. in Molecular and Cell Biology and B.S. in Business Administration from the University of California, Berkeley. Mr. Tong's investment and board experience in the biopharmaceutical industry contributed to our board of directors' conclusion that he should serve as a director of our company.

Family Relationships

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

Board Composition and Election of Directors

Director Independence

Our board of directors currently consists of seven members. Our board of directors has determined that all of our directors, other than Mr. Kuan, are independent directors in accordance with the listing requirements of the Nasdaq Stock Market (Nasdaq). The Nasdaq independence definition includes a series of objective tests, including 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

Nasdaq rules, our board of directors has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of the 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 business and personal activities and relationships as they may relate to us and our management. There are no family relationships among any of our directors or executive officers.

Classified Board of Directors

In accordance with the terms of our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered, three-year terms. At each annual meeting of stockholders, the directors whose terms then expire will be eligible for reelection until the third annual meeting following reelection. Our directors are divided among the three classes as follows:

- the Class I directors are Mr. Kuan, Dr. Mulé and Dr. Post, and their terms will expire at our annual meeting of stockholders in 2025;
- the Class II directors are Ms. Song and Mr. Tong, and their terms will expire at our annual meeting of stockholders in 2026; and
- the Class III directors are Ms. Graf and Dr. Liu, and their terms will expire at our annual meeting of stockholders in 2027.

Our amended and restated certificate of incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors. 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 board of directors or a change in control of our company. Our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of our outstanding voting stock then entitled to vote in an election of directors.

Board Leadership Structure

Our board of directors is currently chaired by Arthur Kuan, our Chief Executive Officer. The board of directors has appointed Leonard Post, Ph.D., as our lead independent director. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. The lead independent director is chosen by the independent members of the board of directors. We believe that this separation of responsibilities ensures the appropriate level of oversight, independence and responsibility is applied to all board decisions.

The duties of our lead independent director include the following:

- chairing meetings of the independent directors in executive session;
- facilitating communications between other members of our board and our chairman and Chief Executive Officer;
- reviewing and approving matters, such as agenda items, schedule sufficiency, and, where appropriate, information provided to other board members;
- consulting with our chairman and Chief Executive Officer on matters relating to corporate governance and board performance; and
- performing such other duties as the board may determine from time to time.

We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing our company. 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

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board of directors as a whole.

Board Committees and Independence

Our board of directors has established three standing committees – audit, compensation and nominating and corporate governance – each of which operates under a charter that has been approved by our board of directors.

Audit Committee

The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements. This committee's responsibilities include, among other things:

- appointing our independent registered public accounting firm;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- approving the audit and non-audit services to be performed by our independent registered public accounting firm;
- reviewing the design, implementation, adequacy and effectiveness of our internal accounting controls and our critical accounting policies;
- discussing with management and the independent registered public accounting firm the results of our annual audit and the review of our quarterly unaudited financial statements;
- reviewing, overseeing and monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to financial statements or accounting matters;
- reviewing on a periodic basis, or as appropriate, any investment policy and recommending to our board of directors any changes to such investment policy;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding our results of operations;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and approving any related party transactions and reviewing and monitoring compliance with our code of conduct and ethics; and
- reviewing and evaluating, at least annually, the performance of the audit committee and its members including compliance of the audit committee with its charter.

The members of our audit committee are Ms. Graf, Dr. Liu and Ms. Song. Ms. Graf serves as the chairperson of the committee. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. Our board of directors has determined that Ms. Graf is an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq listing standards. Our board of directors has determined that each of Ms. Graf, Dr. Liu and Ms. Song is independent under the applicable rules of the SEC and Nasdaq. Upon the listing of our common stock on Nasdaq, the audit committee will operate under a written charter that satisfies the applicable standards of the SEC and Nasdaq.

Compensation Committee

Our compensation committee approves policies relating to compensation and benefits of our officers and employees. The compensation committee approves corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers, evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also approves the issuance of stock options and other awards under our equity plans. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

The members of our compensation committee are Dr. Liu, Dr. Post and Ms. Song. Ms. Song serves as the chairperson of the committee. Our board of directors has determined that each of Dr. Liu, Dr. Post and Ms. Song is independent under the applicable Nasdaq listing standards and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act. Upon the listing of our common stock on Nasdaq, the compensation committee will operate under a written charter, which the compensation committee will review and evaluate at least annually.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for assisting our board of directors in discharging the board of directors' responsibilities regarding the identification of qualified candidates to become board members, the selection of nominees for election as directors at our annual meetings of stockholders (or special meetings of stockholders at which directors are to be elected), and the selection of candidates to fill any vacancies on our board of directors and any committees thereof. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies, reporting and making recommendations to our board of directors concerning governance matters, reviewing and assisting the board of directors with oversight of matters relating to environmental, social and governance matters affecting the company and oversight of the evaluation of our board of directors. The members of our nominating and corporate governance committee are Ms. Graf, Dr. Post and Mr. Tong. Mr. Tong serves as the chairperson of the committee. Our board of directors has determined that each of Ms. Graf, Dr. Post and Mr. Tong is independent under the applicable Nasdaq listing standards. The nominating and corporate governance committee operates under a written charter, which the nominating and corporate governance committee will review and evaluate at least annually.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been one of our officers or employees. None of our executive officers currently serves, or has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Board Diversity

Our nominating and corporate governance committee is responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current

members) for election or appointment, the nominating and corporate governance committee and the board of directors will take into account many factors, including the following:

- personal and professional integrity, ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly-held company;
- experience as a board member or executive officer of another publicly-held company;
- strong finance experience;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience;
- experience relevant to our business industry and with relevant social policy concerns; and
- relevant academic expertise or other proficiency in an area of our business operations.

Our board of directors evaluates each individual in the context of the board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Prohibition Against Pledging and Hedging

We maintain an insider trading compliance policy that prohibits our officers, directors and employees pledging our stock as collateral to secure loans and from engaging in hedging transactions, including prepaid variable forward contract, equity swaps, collars and exchange funds. It further prohibits margin purchases of our stock or placing our stock in a margin account, short sales of our stock, and any transactions in puts, calls or other derivative securities involving our stock.

Attendance by Members of the Board of Directors at Meetings

There were 4 meetings of the Board during the fiscal year ended December 31, 2023. During the fiscal year ended December 31, 2023, each director attended at least 75% of the aggregate of all meetings of the Board, and each director attended as least 75% of meetings of the committees on which such director served during the period in which he or she served as a director.

Communications from Stockholders

The Board will give appropriate attention to written communications that are submitted by stockholders, and will respond if and as appropriate. Our Secretary is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to the directors as he considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that our Secretary and Chairman of the Board consider to be important for the directors to know. In general, communications relating to corporate governance and long-term corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which we tend to receive repetitive or duplicative communications. Stockholders who wish to send communications on any topic to the Board should address such communications to the Board in writing: c/o Secretary, CG Oncology, Inc., 400 Spectrum Center Drive, Suite 2040, Irvine, California 92618.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar function. Our code of business conduct and ethics will be available under

the Corporate Governance section of our website at https://cgoncology.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. We have included our website address in this Annual Report solely as an inactive textual reference. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

Item 11. Executive Compensation.

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below. In 2023, our "named executive officers," which consist of our principal executive officer during 2023 and our two next most highly compensated executive officers during 2023, and their positions were as follows:

- Arthur Kuan, Chairman and Chief Executive Officer;
- Ambaw Bellete, President and Chief Operating Officer; and
- Vijay Kasturi, M.D., Chief Medical Officer.

Mr. Bellete joined the company as President and Chief Operating Officer in July 2023 and Dr. Kasturi joined as Chief Medical Officer in August 2023. Corleen Roche, our Chief Financial Officer and Secretary, commenced employment in January 2024 and is therefore not included as a named executive for 2023. However, we describe the employment arrangements with Ms. Roche in connection with her commencement of employment below.

Summary Compensation Table

The following table presents summary information regarding compensation earned with respect to the fiscal year ended December 31, 2023 by our named executive officers.

2023 Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)[3]	Total ($)
Arthur Kuan	2023	449,000	—	3,293,022	189,000 [4]	2,974	3,933,996
Chairman and Chief Executive Officer	2022	394,000	—	694,269	140,000 [2]	1,130	1,229,399
Ambaw Bellete, *President and Chief Operating Officer*[6]	2023	322,000	189,500 [5]	1,967,465	179,740 [4]	369,970	3,028,675
Vijay Kasturi, *Chief Medical Officer*[6]	2023	152,000	56,000 [5]	2,144,844	87,448 [4]	4,240	2,444,532

(1) The amounts reported in the "Option Awards" column represent the aggregate grant date fair value of the stock options awarded to our named executive officers during the applicable fiscal year, calculated in accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC) Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in our financial statements in this Annual Report. The amounts reported in this column reflect the accounting cost for the stock options and do not reflect the actual economic value that will be realized by the individual upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such awards. See the subsection "—Narrative to Summary Compensation Table—Equity-Based Incentive Awards" in this Annual Report.

(2) Amount reflects a performance bonus earned by Mr. Kuan in 2022, which was paid in early 2023.

(3) Amounts reflect $9,919 and $2,217 in 401(k) matching contributions for Mr. Bellete and Dr. Kasturi, respectively, $760, $317 and $253 in company-paid premiums for long-term disability insurance for Mr. Kuan, Mr. Bellete and Dr. Kasturi, respectively, $666, $278 and $222 in company-paid premiums for life insurance for Mr. Kuan, Mr. Bellete and Dr. Kasturi, respectively, and $1,548 related to a company-paid holiday-related gift for each of Mr. Kuan, Mr. Bellete and Dr. Kasturi. Amount for Mr. Bellete also reflects $357,908 for his services as a consultant to the company during 2023 prior to his commencement of employment.

(4) Amounts reflect performance bonuses earned by each executive in 2023, which were paid in March 2024.

(5) Amounts reflect one-time sign-on bonuses paid to Mr. Bellete and Dr. Kasturi in connection with their commencement of employment with the company in July 2023 and August 2023, respectively.

(6) The annual base salaries for Mr. Bellete and Dr. Kasturi were each prorated for the portion of the year employed in 2023.

Narrative to Summary Compensation Table

Annual Base Salary

The compensation of our named executive officers is generally determined and approved by our board of directors. The 2023 base salaries of each of our named executive officers are described under the subsection titled "—Employment Arrangements with our Named Executive Officers" below.

Annual Bonus

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is based on the extent to which we achieve the corporate goals that our board of directors establishes each year. At the end of the year, our board of directors reviews our performance against each corporate goal and determines the extent to which we achieved each of our corporate goals.

For 2023, Mr. Kuan, Mr. Bellete, and Dr. Kasturi were each eligible to earn a target annual bonus equal to 40% of their respective annual base salaries. The annual bonus for Dr. Kasturi will be prorated for the portion of the year employed in 2023.

The corporate goals the board of directors established for 2023 related to regulatory, clinical and development goals, as well as operational objectives. Bonuses are determined and paid in the first quarter of the following year. For 2023, the bonuses for our named executive officers paid in the first quarter of 2024 are reflected in the Summary Compensation Table above.

In connection with our initial public offering, the target annual bonuses for Mr. Kuan and Mr. Bellete increased to 55% and 45% of annual base salary, retroactive to January 1, 2024.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees, including our executive officers. The board of directors or an authorized committee thereof is responsible for approving equity grants.

Prior to our initial public offering, we granted stock options pursuant to our 2015 Equity Incentive Plan (2015 Plan) and our 2022 Incentive Award Plan (2022 Plan). Following our initial public offering, we grant equity awards under the terms of our 2024 Incentive Award Plan (2024 Plan). All options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award. Our stock option grants generally vest over a four-year period and may be subject to acceleration of vesting and exercisability under certain termination and change in control events. In addition, from time to time our board of directors has also granted performance-based stock options, the vesting of which is tied to key clinical, operational or regulatory milestones.

In June 2023, Mr. Bellete was granted an option to purchase 432,311 shares of our common stock pursuant to our 2022 Plan. The option has an exercise price of $3.72 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation, and vests over a period of four years, with 25% of the shares underlying the option vesting on the first-year anniversary of the vesting commencement date (July 9, 2023), and the remaining shares vesting in equal monthly installments over the subsequent three-year period thereafter, subject to Mr. Bellete's continuous service with us as of each such vesting date. In addition, Mr. Bellete was also granted an option to purchase 121,833 shares of our common stock pursuant to our 2022 Plan. The option has an exercise price of $3.72 per share and, subject to Mr. Bellete's continuous service with us as of each such

vesting date, vests as follows: (1) 29,365 shares vested upon the successful completion of our initial public offering of the company's common stock on a public exchange by December 31, 2026, (2) 29,365 shares vest upon the enrollment of the first patient in the IR trial by December 31, 2026, (3) 16,869 shares vest upon the company achieving commercial organization readiness by December 31, 2026, as determined by our board of directors, (4) 29,365 shares vest upon the approval by the FDA of a BLA with respect to cretostimogene, provided such BLA approval occurs on or before December 31, 2026, and (5) 16,869 shares vest upon the company's achievement of the first successful commercial sale by December 31, 2026.

In August 2023, Dr. Kasturi was granted an option to purchase 443,628 shares of our common stock pursuant to our 2022 Plan. The option has an exercise price of $5.06 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation, and vests over a period of four years, with 25% of the shares underlying the option vesting on the first-year anniversary of the vesting commencement date (August 14, 2023), and the remaining shares vesting in equal monthly installments over the subsequent three-year period thereafter, subject to Dr. Kasturi's continuous service with us as of each such vesting date. In addition, Dr. Kasturi was also granted an option to purchase 49,292 shares of our common stock pursuant to our 2022 Plan. The option has an exercise price of $5.06 per share and, subject to Dr. Kasturi's continuous service with us as of each such vesting date, vests as follows: (1) 24,646 shares vest upon the filing with the FDA of the company's BLA with respect to cretostimogene, provided that such BLA filing occurs on or before December 31, 2025, and (2) 24,646 shares vest upon the approval by the FDA of a BLA with respect to cretostimogene, provided that such BLA approval occurs on or before December 31, 2026.

In October 2023, Mr. Kuan was granted an option to purchase 524,383 shares of our common stock pursuant to our 2022 Plan. The option has an exercise price of $6.67 per share, which was the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation, and vests in equal monthly installments over a period of four years following the grant date, subject to Mr. Kuan's continuous service with us as of each such vesting date.

In December 2023, our compensation committee approved the grant of stock options pursuant to the 2022 Plan to our named executive officers as follows: Mr. Kuan, 83,901 options; Mr. Bellete, 52,438 options; and Dr. Kasturi, 36,706 options. Such stock options have an exercise price of $12.59 per share, which was the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation, and vest in equal monthly installments over a period of four years following the grant date, and in each case subject to such executive's continuous service with us through the applicable vesting date.

In January 2024, in connection with the commencement of employment of Corleen Roche, our Chief Financial Officer, our board of directors approved a grant of stock options to Ms. Roche to purchase 492,920 shares of our common stock pursuant to our 2024 Plan, which grant became effective on January 24, 2024. The option has an exercise price per share of $19.00, which was the initial price to the public of a share of common stock in our initial public offering. The option vests over a four-year period, with 25% of the shares vesting on the date that is 12 months after the vesting commencement date (January 16, 2024), and the remaining shares vesting in 36 equal monthly installments thereafter, subject to Ms. Roche's continuous service with us as of each such vesting date.

Outstanding Equity Awards at 2023 Fiscal Year End

The following table presents information regarding the outstanding stock options held by each of our named executive officers as of December 31, 2023.

	Option Awards					
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable[1]	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date
Arthur Kuan	04/19/21	167,483	—	—	$ 1.72	04/19/31
	10/19/22	8,521	289,722[2]	—	$ 2.29	10/19/32
	10/09/23	32,773	491,609[2]	—	$ 6.67	10/09/33
	12/13/23	—	83,901[3]	—	$ 12.59	12/13/33
Ambaw Bellete	06/14/23	—	432,311[4]	—[5]	$ 3.72	06/14/33
	06/14/23	—	—	121,831[5]	$ 3.72	06/14/33
	12/13/23	—	52,438[3]	—	$ 12.59	12/13/33
Vijay Kasturi, M.D.	08/15/23	—	443,628[4]	—[6]	$ 5.06	08/15/33
	08/15/23	—	—[3]	49,292[6]	$ 5.06	08/15/33
	12/13/23	—	36,706	—	$ 12.59	12/13/33

(1) These awards are subject to potential acceleration of vesting in connection with a qualifying termination of employment following a change in control, as described under the subsection titled "—Employment Arrangements with our Named Executive Officers" below.

(2) The options vest in equal monthly installments over a period of four years following the vesting commencement date (October 19, 2022 for Mr. Kuan's options granted on October 19, 2022 and September 20, 2023 for Mr. Kuan's options granted on October 9, 2023), subject to Mr. Kuan's continuous service with us through each such vesting date.

(3) The options vest in equal monthly installments over a period of four following the vesting commencement date (December 13, 2023), subject to the executive's continuous service with us through each such vesting date.

(4) The options vest over a period of four years, with 25% of the shares subject to the options vesting on the first anniversary of the vesting commencement date (July 9, 2023 for Mr. Bellete and August 14, 2023 for Dr. Kasturi), and the remaining shares vesting in equal monthly installments thereafter over the subsequent three-year period, subject, respectively, to Mr. Bellete and Dr. Kasturi's continuous services with us through each such vesting date.

(5) The option vests as follows: (i) 29,365 shares vested upon successful completion of our initial public offering of the company's common stock on a public exchange by December 31, 2026, (ii) 29,365 shares vest upon the enrolment of the first patient in the IR trial by December 31, 2026, (iii) 16,868 shares vest upon the company achieving commercial organization readiness by December 31, 2026, as determined by our board of directors, (iv) 29,365 shares vest upon the approval by the FDA of a BLA with respect to cretostimogene, provided such BLA approval occurs on or before December 31, 2026, and (v) 16,868 shares vest upon the company's achievement of the first successful commercial sale by December 31, 2026.

(6) The option vests as follows: (i) 24,646 shares vest upon the filing with the FDA of a BLA with respect to cretostimogene, provided that such BLA filing occurs on or before December 31, 2025, and (ii) 24,646 shares vest upon the approval by the FDA of the company's BLA with respect to cretostimogene, provided that such BLA approval occurs on or before December 31, 2026.

Employment Arrangements with Our Executive Officers

We have entered into employment agreements with certain of our executive officers, including our named executive officers, which govern the terms of their employment with us. Pursuant to their employment agreements, Mr. Kuan, Mr. Bellete, Dr. Kasturi, and Ms. Roche are each entitled to an annual base salary of $450,000, $430,000, $415,000, and $450,000, respectively. The base salaries for Mr. Kuan, Mr. Bellete and Dr. Kasturi were increased to $625,000, $495,000 and $465,000, respectively, effective January 1, 2024. In addition, in accordance with their employment agreements, Mr. Kuan, Mr. Bellete, Ms. Roche and Dr. Kasturi are eligible to earn an annual bonus at a target amount of40% of their base salaries actually paid for the year to which such annual bonus relates, subject to the achievement of performance objectives as determined by our board of directors. The target annual bonuses for Mr. Kuan and Mr. Bellete were increased to 55% and 45% of their annual base salaries, effective January 1, 2024.

Pursuant to their employment agreements, Mr. Bellete, Dr. Kasturi and Ms. Roche also received a sign on bonus in the amount of $125,000, $50,000 and $30,000, respectively, subject to repayment if the executive is terminated for cause or resigns without good reason prior to completing 12 months of service, for Mr. Bellete, and 24 months of

service for Dr. Kasturi and Ms. Roche. Additionally, Mr. Bellete is also eligible to receive a relocation reimbursement of up to $90,000 should the company require Mr. Bellete to relocate to the Orange County, California area.

Regardless of the manner in which our executive officers' employment terminates, they are entitled to receive certain accrued amounts previously earned during their employment, including unpaid salary, reimbursement of expenses owed, and accrued but unpaid paid time off and any continuation of benefits required by applicable law. In addition, our executive officers are entitled to certain severance benefits under their employment agreements, subject to their execution of a release of claims and compliance with post-termination obligations.

Arthur Kuan and Ambaw Bellete

Messrs. Kuan and Bellete's employment agreements provide for severance benefits for certain terminations that arise during and outside of a change in control period (as defined below). Upon a termination without cause outside of the period commencing upon a change in control and continuing until 18 months after such change in control (such period, the change in control period), Messrs. Kuan and Bellete are entitled to (1) an amount in cash equal to their annual base salary, payable in a lump sum, (2) payment or reimbursement of the COBRA premiums for Messrs. Kuan and Bellete and their respective eligible dependents, or if COBRA is not available under our group health plan, a cash amount equal to such payments or reimbursements, for a maximum period of up to 12 months from the date of their termination of employment, and (3) an amount in cash equal to their target annual bonus, prorated for the portion of the year that elapsed prior to the date of their termination of employment, payable in a lump sum. Additionally, upon a termination without cause occurring outside of the change in control period, Mr. Bellete is entitled to outplacement services for 12 months, up to a maximum cost of $20,000.

In addition, except with respect to Mr. Bellete's option award of 432,311 shares granted on June 14, 2023 (the Bellete Initial Option), upon a termination without cause outside of the change in control period, Messrs. Kuan and Bellete are entitled to accelerated vesting of the unvested portion of company equity awards that would have vested during the 12 months following the date of their termination of employment had they continued in employment during such period; provided, however, that any performance-based equity awards shall remain subject to attainment of the relevant performance goals. With respect to the Bellete Initial Option, Mr. Bellete is entitled to the following: (1) if the termination without cause occurs prior to the first anniversary of Mr. Bellete's start date, accelerated vesting of the portion of the Bellete Initial Option that would have vested during the 12 months following the date of such termination had he continued in employment during such period, (2) if such termination occurs after the first anniversary of Mr. Bellete's start date but prior to the second anniversary of his start date, accelerated vesting of the portion of the Bellete Initial Option that would have vested during the 18 months following the date of such termination had he continued in employment during such period, and (3) if such termination occurs after the second anniversary of Mr. Bellete's start date, accelerated vesting of any unvested portion of the Bellete Initial Option.

Upon a termination without cause or a resignation for good reason within the change in control period, Mr. Kuan is entitled to (1) an amount in cash equal to 1.5 times his annual base salary, payable in a lump sum, (2) payment or reimbursement of the COBRA premiums for Mr. Kuan and his eligible dependents, or if COBRA is not available under our group health plan, a cash amount equal to such payments or reimbursements, for a maximum period of up to 18 months from the date of Mr. Kuan's termination of employment, (3) an amount in cash equal to 1.5 times his target annual bonus, payable in a lump sum, and (4) full accelerated vesting of all unvested company equity awards; provided, however, that any performance-based equity awards shall remain subject to attainment of the relevant performance goals.

Upon a termination without cause or a resignation for good reason within the change in control period, Mr. Bellete is entitled to (1) an amount in cash equal to his annual base salary, payable in a lump sum, (2) payment or reimbursement of the COBRA premiums for Mr. Bellete and his eligible dependents, or if COBRA is not available under our group health plan, a cash amount equal to such payments or reimbursements, for a maximum period of up to 12 months from the date of Mr. Bellete's termination of employment, (3) an amount in cash equal to his target annual bonus, payable in a lump sum, (4) full accelerated vesting of all unvested company equity awards (provided, however, that any performance-based equity awards shall remain subject to attainment of the relevant performance goals), and (5) outplacement services for 18 months, up to a maximum cost of $20,000.

Vijay Kasturi, M.D. and Corleen Roche

Dr. Kasturi and Ms. Roche's employment agreements provide for severance benefits for certain terminations that arise during and outside of a change in control period. Upon a termination without cause outside of the change in control period, Dr. Kasturi and Ms. Roche are entitled to (1) an amount in cash equal to 0.75 times their annual base salary, payable in a lump sum, (2) payment or reimbursement of the COBRA premiums for Dr. Kasturi and Ms. Roche and their respective eligible dependents, or if COBRA is not available under our group health plan, a cash amount equal to such payments or reimbursements, for a maximum period of up to 9 months from the date of their termination of employment, (3) an amount in cash equal to their target annual bonus, prorated for the portion of the year that elapsed prior to the date of their termination of employment, payable in a lump sum, and (4) accelerated vesting of the unvested portion of company equity awards that would have vested during the 9 months following the date of Dr. Kasturi or Ms. Roche's termination of employment they he continued in employment with the company during such period; provided, however, that any performance-based equity awards shall remain subject to attainment of the relevant performance goals.

Upon a termination without cause or a resignation for good reason within the change in control period, Dr. Kasturi and Ms. Roche would be entitled to (1) an amount in cash equal to their annual base salary, payable in a lump sum, (2) payment or reimbursement of the COBRA premiums for Dr. Kasturi and Ms. Roche and their respective eligible dependents, or if COBRA is not available under our group health plan, a cash amount equal to such payments or reimbursements, for a maximum period of up to 12 months from the date of their termination of employment, (3) an amount in cash equal to their target annual bonus, payable in a lump sum, and (4) full accelerated vesting of all unvested company equity awards; provided, however, that any performance-based equity awards shall remain subject to attainment of the relevant performance goals.

Health and Welfare Benefits; Perquisites

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, disability, and life insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Code. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Under the 401(k) plan, we provide matching contributions equal to 100% of the first 4% of eligible compensation deferred by our employees, not to exceed 1% of an employee's eligible compensation. Our board of directors may elect to adopt qualified or nonqualified retirement plans in the future, if it determines that doing so is in our best interests.

Clawback Policy

We have adopted a compensation recovery policy that is compliant with the Nasdaq Listing Rules, as required by the Dodd-Frank Act.

Non-Employee Director Compensation

We provide a $36,000 cash retainer, paid in quarterly installments, to certain non-employee directors for their service on our board of directors. We also have a policy of reimbursing all of our non-employee directors for their reasonable out-of-pocket expenses in connection with attending board of directors and committee meetings.

We also from time to time provide equity compensation to certain non-employee directors for their service on our board of directors. On June 14, 2023, Drs. Mulé and Post were granted options to purchase 7,865 shares and 15,731 shares, respectively, of our common stock. The options have an exercise price of $3.72 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The options vest over a period of three years in equal monthly installments beginning on the first monthly anniversary of the vesting commencement date (June 14, 2023), subject to Dr. Mulé and Dr. Post's continuous service with us as of each such vesting date.

Additionally, on November 20, 2023, Susan Graf was appointed as a member of our board of directors and was granted an option to purchase 104,876 shares of our common stock, which has an exercise price of $7.82 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The option vests over a period of three years in equal monthly installments beginning on the first monthly anniversary of the vesting commencement date (November 14, 2023), subject to Ms. Graf's continuous service with us as of each such vesting date.

On December 13, 2023, Dr. Mulé was granted an option to purchase 15,731 shares of our common stock, which has an exercise price of $12.59 per share, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The option vests over a period of three years in equal monthly installments following the vesting commencement date (December 13, 2023), subject to Dr. Mulé's continuous service with us as of each such vesting date.

The following table sets forth information regarding compensation earned with respect to the fiscal year ended December 31, 2023 by each individual who served as a non-employee director during such fiscal year.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[5]	All Other Compensation ($)	Total ($)
Brian Liu	—	—	—	—
Susan Graf[1][2]	4,696	594,343	—	599,039
James J. Mulé, IPh.D.[1]	36,000	162,004	—	198,004
Osamu Nakanishi, Ph.D.[3]	—	—	—	—
Leonard Post, Ph.D.[1]	36,000	41,541	—	77,541
Jue Pu[4]	—	—	—	—
Simone Song	—	—	—	—
Victor Tong, Jr.	—	—	—	—

(1) As of December 31, 2023, Ms. Graf and Drs. Mulé and Post each held options to purchase 104,876 shares, 86,052 shares, and 150,808 shares, respectively, of our common stock.
(2) Ms. Graf was appointed as a director in November 2023. Ms. Graf's annual cash retainer paid in 2023 was prorated to reflect the portion of the year Ms. Graf served as a director in 2023.
(3) Dr. Nakanishi ceased serving as a director in October 2023.
(4) Ms. Pu ceased serving as a director in October 2023.
(5) The amounts reported in the "Option Awards" column represent the aggregate grant date fair value of the stock options awarded to our non-employee directors during the applicable fiscal year, calculated in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in our financial statements included elsewhere in this Annual Report. The amounts reported in this column reflect the accounting cost for the stock options and do not reflect the actual economic value that will be realized by the individual upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such awards.

Director Compensation Program

In connection with our initial public offering, our board of directors adopted and our stockholders approved our non-employee director compensation program. The non-employee director compensation program provides for annual retainer fees and equity awards for our non-employee directors. Each non-employee director receives an annual retainer of $40,000, with the non-employee director serving as chair of the board of directors or lead independent director receiving an additional annual retainer of $30,000. The non-employee directors serving as the chairs of the audit, compensation and nominating and corporate governance committees receive additional annual retainers of $15,000, $12,000 and $10,000, respectively. Non-employee directors serving as members of the audit, compensation

and nominating and corporate governance committees receive additional annual retainers of $7,500, $6,000 and $5,000, respectively. Non-employee directors commencing service following our initial public offering will receive initial grants of options to purchase 44,500 shares of our common stock, vesting monthly over three years, upon election or appointment to the board of directors. Each year on the date of each annual meeting, each non-employee director will receive an annual grant of options to purchase 22,250 shares of our common stock, vesting in substantially equal monthly installments over the 12 months following the date of grant (or, in the event the next annual meeting of our stockholders occurs prior to the first anniversary of the date of grant, any remaining unvested portion of the annual award will vest on the date of such annual meeting of our stockholders). Awards to our non-employee directors will also vest in the event of a change in control or upon a non-employee director's death or disability.

Compensation under our non-employee director compensation program will be subject to the annual limits on non-employee director compensation set forth in the 2024 Plan (which limits will not apply to any non-employee director that serves in any additional capacity with the company for which he or she receives compensation or any compensation paid to any non-employee director prior to 2025). As provided in the 2024 Plan, our board of directors or its authorized committee may make exceptions to this limit for individual non-employee directors as the board of directors or its authorized committee may determine in its discretion.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director's duty of loyalty to us or our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that if Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws also provide that we shall have the power to indemnify our employees and agents to the fullest extent permitted by law. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our amended and restated bylaws would permit indemnification. We have obtained directors' and officers' liability insurance.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers.

The above description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is not complete and is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to this Annual Report.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and

officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

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

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 25, 2024, by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Applicable percentage ownership is based on 66,636,252 shares of common stock outstanding on March 25, 2024. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or other rights held by such person that are currently exercisable or that will become exercisable or otherwise vest within 60 days of March 25, 2024 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o CG Oncology, Inc., 400 Spectrum Center Drive, Suite 2040, Irvine, CA 92618. We believe, based on information provided to us, that each of

the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders		
Entities affiliated with ORI Capital[1]	4,941,368	7.4%
Decheng Capital Global Life Sciences Fund IV, L.P.[2]	5,358,812	8.0%
Entities affiliated with Longitude Venture Partners[3]	4,662,281	7.0%
Kissei Pharmaceutical Co., Ltd.[4]	3,543,533	5.3%
Entities affiliated with Foresite Capital[5]	3,595,203	5.4%
TCG Crossover Fund I, L.P.[6]	3,570,206	5.4%
Named Executive Officers and Directors		
Arthur Kuan[7]	308,508	*
Ambaw Bellete[8]	26,218	*
Vijay Kasturi[9]	3,609	*
Brian Liu, M.D.	—	—
Susan Graf	—	—
James J. Mulé, IPh.D.[10]	61,794	*
Leonard Post, Ph.D.[11]	139,009	*
Simone Song[12]	5,555,296	8.3%
Victor Tong, Jr.	—	—
All executive officers and directors as a group (10 persons)[13]	1,155,066	1.8%

* Less than 1%.

(1) Consists of (i) 1,011,192 shares of common stock held by Unique Diamond Investments Limited and (ii) 3,930,176 shares of common stock held by Charming Jade Limited. Unique Diamond Investments Limited is a wholly-owned subsidiary of ORI Healthcare Fund, L.P. ORI Capital Inc. is the general partner of ORI Healthcare Fund, L.P. and may be deemed to have voting, investment and dispositive power with respect to these securities. ORI Capital Inc. is a wholly-owned subsidiary of ORI Capital Holding Inc, which is a wholly-owned subsidiary of Healthcare Seed Limited. Charming Jade Limited is a wholly-owned subsidiary of ORI Healthcare Fund II, L.P. ORI Capital II Inc. is the general partner of ORI Healthcare Fund II, L.P. and may be deemed to have voting, investment and dispositive power with respect to these securities. ORI Capital II Inc. is a wholly-owned subsidiary of ORI Capital Holding Inc, which is a wholly-owned Subsidiary of Healthcare Seed Limited. Ms. Song is the sole owner of Healthcare Seed Limited. The business address for Ms. Song and these entities is C/O Room Nos. 4727-4734, 47/F, Sun Hung Kai Centre, 30 Harbour Road, Wanchai, Hong Kong.

(2) Consists of 5,358,812 shares of common stock held by Decheng Capital Global Life Sciences Fund IV, L.P. Decheng Capital Management IV (Cayman), LLC (the Decheng GP) is the general partner of the Fund. Xiangmin Cui is the manager of the Decheng GP. Each of the Fund, the Decheng GP and Dr. Cui may be deemed to beneficially own the securities held by the Fund. Each of the Fund, the Decheng GP and Dr. Cui disclaim beneficial ownership of these securities, except to the extent of their respective pecuniary interests therein. The business address for Decheng is 3000 Sand Hill Road, Building 2, Suite 110, Menlo Park, California 94025.

(3) Based on the Schedule 13-G, filed on February 5, 2024 by Longitude Capital Partners IV, L.P. (LCPIV). Consists of (i) 3,190,476 shares of common stock held by Longitude Venture Partners IV, L.P. (LVPIV) and (ii) 1,471,805 shares of common stock held by Longitude Prime Fund, L.P. (LPF). Longitude Capital Partners IV, LLC (LCPIV) is the general partner of LVPIV and may be deemed to have voting, investment and dispositive power with respect to these securities. Longitude Prime Partners, LLC (LPP) is the general partner of LPF and may be deemed to have voting, investment and dispositive power with respect to the securities held by LPF. Juliet Tammenoms Bakker and Patrick G. Enright are the managing members of LCPIV and LPP and may each be deemed to share voting, investment and dispositive power with respect to these securities. Each of LPP, LCPIV, Ms. Tammenoms Bakker and Mr. Enright disclaim beneficial ownership of such shares except to the extent of their respective pecuniary interests therein. The business address for these individuals and entities is 2740 Sand Hill Road, 2nd Floor, Menlo Park, California 94025.

(4) Based on the Schedule 13-G, filed on March 14, 2024 by Kissei Pharmaceutical Co. Ltd. Consists of 3,543,533 shares of common stock held by Kissei Pharmaceutical Co., Ltd. (Tokyo Stock Exchange, stock code: 4547). The business address for Kissei is 19-48 Yoshino, Matsumoto City, Nagano, Japan.

(5) Based on the Schedule 13-G, filed on February 5, 2024 by Foresite Capital Fund V, L.P. Consists of (i) 692,550 shares of common stock held by Foresite Capital Fund V, L.P. (Fund V), (ii) 2,045,103 shares of common stock held by Foresite Capital Fund VI, L.P. (Fund VI) and (iii) 857,550 shares of common stock held by Foresite Capital Opportunity Fund V, L.P. (Opportunity Fund V, and, together with Fund V and Fund VI, Foresite). Foresite Capital Management V LLC (FCM V) is the general partner of Fund V. Foresite Capital Management VI, LLC (FCM VI) is the general partner of Fund VI. Foresite Capital Opportunity Management V, LLC (FCOM V) is the general partner of Opportunity Fund V. FCM V, FCM VI and FCOM V may be deemed to have sole voting and dispositive power over these shares. James B. Tananbaum is the sole managing member of FCM V, FCM VI and FCOM V and may be deemed to have sole voting and dispositive power over these shares. Each of FCM V, FCM VI, FCOM V and Dr. Tananbaum disclaim beneficial ownership of these securities, except to the extent of their respective pecuniary interests therein. The address of Foresite, FCM VI, FCM V, FCOM V and Dr. Tananbaum is 900 Larkspur Landing Circle, Suite 150 Larkspur, CA 94939.

(6) Based on the Schedule 13-G, filed on February 9, 2024 by TCG Crossover GP I. Consists of 3,570,206 shares of common stock held by TCG Crossover Fund I, L.P. TCG Crossover GP I, LLC (TCG Crossover GP I) is the general partner of TCG Crossover Fund I, L.P. (TCG Crossover I) and may be deemed to have voting, investment, and dispositive power with respect to these securities. Chen Yu is the sole managing member of TCG Crossover GP I and may be deemed to share voting, investment and dispositive power with respect to these securities. The business address for TCG Crossover GP I, TCG Crossover I and Mr. Yu is 705 High St., Palo Alto, CA 94301.
(7) Consists of 36,151 shares of common stock held directly and 272,357 shares of common stock underlying options held by Mr. Kuan that are exercisable as of March 25, 2024 or that will become exercisable within 60 days after such date.
(8) Consists of 26,218 shares of common stock underlying options held by Mr. Bellete that are exercisable as of March 25, 2024 or that will become exercisable within 60 days after such date.
(9) Consists of 1,315 shares of common stock held directly and 2,294 shares of common stock underlying options held by Dr. Kasturi that are exercisable as of March 25, 2024 or that will become exercisable within 60 days after such date.
(10) Consists of 61,794 shares of common stock underlying options held by Dr. Mulé that are exercisable as of March 25, 2024 or that will become exercisable within 60 days after such date.
(11) Consists of 139,009 shares of common stock underlying options held by Dr. Post that are exercisable as of March 25, 2024 or that will become exercisable within 60 days after such date.
(12) Consists of (i) 1,011,192 shares of common stock held by Unique Diamond Investments Limited, (ii) 3,930,176 shares of common stock held by Charming Jade Limited and (iii) 613,928 shares of common stock held directly by Ms. Song, as further described in footnote 1 above.
(13) Includes the shares described in footnotes 7 through 12, and excludes shares held by Unique Diamond Investments Limited and Charming Jade Limited, and included 2,000 shares of common stock held by others.

Equity Compensation Plan Information

The following table provides information on our equity compensation plans as of December 31, 2023, adjusted to reflect a 1-for-9.535 reverse stock split of our issued and outstanding common stock and stock option awards effected on January 16, 2024. The following table does not include information regarding our 2024 Incentive Award Plan (2024 Plan) or our 2024 Employee Stock Purchase Program which became effective at the time of our initial public offering. As of December 31, 2023, we maintained two equity compensation plans, consisting of our 2015 Equity Incentive Plan (the 2015 Plan) and our 2022 Incentive Award Plan (the 2022 Plan) under which shares of our common stock were authorized for issuance detailed as follows:

Plan Category	Number of securities to be issued upon the exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	5,532,871[1]	$4.12[1][2]	124,136[3]
Equity compensation plans not approved by security holders	—	—	—
Total	5,532,871	$ 4.12	124,136

(1) Includes 1,760,634 shares of common stock that were subject to outstanding option awards as of December 31, 2023 under the 2015 Plan and 3,772,237 shares of common stock that were subject to outstanding option awards as of December 31, 2023 under the 2022 Plan.
(2) Represents the weighted-average exercise price of outstanding options.
(3) Includes 124,136 shares of common stock which were available for issuance under the 2022 Plan as of December 31, 2023. As of December 31, 2023, we were no longer permitted to grant awards under the 2015 Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The following includes a summary of transactions since January 1, 2022 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 and one percent of the average of our total assets as of December 31, 2023, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control

and other arrangements, which are described under Item 11 of Part III of this Annual Report. We also describe below certain other transactions with our directors, executive officers and stockholders.

Redeemable Convertible Preferred Stock Financings

Series E Redeemable Convertible Preferred Stock Financing. In September 2022, we entered into a Series E redeemable convertible preferred stock purchase agreement, pursuant to which in closings in September 2022 and October 2022 we sold to investors, in private placements, an aggregate of 112,422,700 shares of Series E redeemable convertible preferred stock. The per share purchase price was $1.0674, and we received gross proceeds of approximately $120 million.

Series F Redeemable Convertible Preferred Stock Financing. In July 2023, we entered into a Series F redeemable convertible preferred stock purchase agreement, pursuant to which in July 2023 we sold to investors, in private placements, an aggregate of 81,587,937 shares of Series F redeemable convertible preferred stock. The per share purchase price was $1.2872, and we received gross proceeds of approximately $105 million.

The following table sets forth the aggregate number of shares acquired by the listed directors, executive officers or holders of more than 5% of our capital stock, or their affiliates. Each outstanding share of redeemable convertible preferred stock identified in the table below will convert into shares of common stock at a ratio of one-for-9.535 upon completion of our initial public offering.

Participants	Series E Redeemable Convertible Preferred Stock	Series F Redeemable Convertible Preferred Stock
5% or greater stockholders[1]		
Entities affiliated with ORI Capital[2]	37,474,236	—
Decheng Capital Global Life Sciences Fund IV, L.P.[3]	21,547,685	4,402,320
Entities affiliated with Foresite Capital[4]	—	23,306,401
Kissei Pharmaceutical Co., Ltd.	—	—
Entities affiliated with Longitude Venture Partners[5]	21,547,685	4,402,320
TCG Crossover Fund I, L.P.	—	23,306,401

(1) Additional details regarding these stockholders and their equity holdings are provided in the section titled "Principal Stockholders."
(2) Represents securities acquired by Unique Diamond Investments Limited and Charming Jade Limited. Simone Song is a Founder and Senior Partner at ORI Capital and a member of our board of directors.
(3) Victor Tong, Jr. is a Managing Director at Decheng and a member of our board of directors.
(4) Represents securities acquired by Foresite Capital Fund V, L.P., Foresite Capital Fund VI, L.P. and Foresite Capital Opportunity Fund V, L.P.
(5) Represents securities acquired by Longitude Prime Fund, L.P. and Longitude Venture Partners IV, L.P. Brian Liu, M.D. is a Managing Director at Longitude Capital Management and a member of our board of directors.

Secondary Stock Sales

In October 2023, Abundant Supply Global Limited, an entity affiliated with ORI Capital, a greater than 5% stockholder of our company, entered into stock transfer agreements with certain other holders of our capital stock pursuant to which Abundant Supply Global Limited sold an aggregate of 27,190,800 shares of Series C redeemable convertible preferred stock at a purchase price of $1.2872 per share for an aggregate purchase price of $34,999,997.84 (the ASGL Secondary Sales). In connection with these transactions, Abundant Supply Global Limited sold 3,107,520 shares of Series C redeemable convertible preferred stock to Decheng Capital Global Life Sciences Fund IV, L.P., a greater than 5% stockholder of our company (Decheng Capital Global), 3,107,520 shares of Series C redeemable convertible preferred stock to TCG Crossover Fund I, L.P., 3,107,520 shares of Series C redeemable convertible preferred stock to Longitude Prime Fund, L.P., an entity affiliated with Longitude Venture Partners, a greater than 5% stockholder of our company, (Longitude Prime), an affiliate of Longitude Venture Partners, and an aggregate of 3,107,520 shares of Series C redeemable convertible preferred stock to entities affiliated with Foresite Capital. In connection with the ASGL Secondary Sales, we entered into a stock transfer agreement with Abundant Supply Global

Limited and each purchaser in January 2024, Abundant Supply Global Limited transferred all of its shares to its affiliate, Unique Diamond Investments Limited.

In August 2023, Longitude Prime entered into a stock transfer agreement with an entity affiliated with a holder of our capital stock pursuant to which Longitude Prime sold 1,756,323 shares of Series C redeemable convertible preferred stock at a purchase price of $0.9073 per share for an aggregate purchase price of $1,593,511.86 (the August 2023 Longitude Secondary Transaction). In July 2023, Longitude Prime entered into a stock transfer agreement with Lepu Holdings Limited pursuant to which Longitude Prime purchased 3,512,646 shares of Series C redeemable convertible preferred stock from Lepu Holdings Limited at a purchase price of $0.9073 per share for an aggregate purchase price of $3,187,023.72 (the July 2023 Longitude Secondary Transaction). Jue Pu, our then-director, was an affiliate of Lepu Holdings Limited at the time of the July 2023 Longitude Secondary Transaction. In connection with the August 2023 Longitude Secondary Transaction and the July 2023 Longitude Secondary Transaction, we entered into stock transfer agreements with Longitude Prime and each counterparty. In May 2023, Longitude Venture Partners IV, L.P, an entity affiliated with Longitude Venture Partners, entered into a common stock transfer agreement with various holders of capital stock pursuant to which Longitude Venture Partners IV, L.P. purchased 8,873,500 shares of common stock at a purchase price of $0.80055 per share for an aggregate purchase price of $7,103,680.43 (the May 2023 Longitude Secondary Transaction). In connection with the May 2023 Longitude Secondary Transaction, we entered into a common stock transfer agreement with Longitude Venture Partners IV, L.P. and each seller pursuant to which, among other things, we waived our right of first refusal to purchase the shares of common stock sold in the transaction.

In July 2023, Decheng Capital Global entered into a stock transfer agreement with Lepu Holdings Limited pursuant to which Decheng Capital Global purchased 3,512,646 shares of Series C redeemable convertible preferred stock from Lepu Holdings Limited at a purchase price of $0.9073 per share for an aggregate purchase price of $3,187,023.72 (the July 2023 Decheng Secondary Transaction). Jue Pu, our then-director, was an affiliate of Lepu Holdings Limited at the time of the July 2023 Decheng Secondary Transaction. In June 2023, Decheng Capital Global entered into a stock transfer agreement with a holder of our capital stock pursuant to which Decheng Capital Global purchased 2,024,725 shares of Series C redeemable convertible preferred stock at a purchase price of $0.91 per share for an aggregate purchase price of $1,842,499.75 (the June 2023 Decheng Secondary Transaction). In connection with the July 2023 Decheng Secondary Transaction and the June 2023 Decheng Secondary Transaction, we entered into stock transfer agreements with Decheng Capital Global and each seller. In May 2023, Decheng Capital Global entered into common stock transfer agreements with various holders of capital stock pursuant to which Decheng Capital Global purchased 8,873,500 shares of common stock at a purchase price of $0.80055 per share for an aggregate purchase price of $7,103,680.44 (the May 2023 Decheng Secondary Transaction). In connection with the May 2023 Decheng Secondary Transaction, we entered into a common stock transfer agreement with Decheng Capital Global and each seller pursuant to which, among other things, we waived our right of first refusal to purchase the shares of common stock sold in the transaction.

Investors' Rights Agreement

We entered into an investors' rights agreement in July 2014, as last amended and restated in July 2023 (the Investors' Rights Agreement), with the holders of our redeemable convertible preferred stock and certain holders of our common stock, including the holders of more than 5% of our capital stock listed above as well as entities with which certain of our directors are affiliated. This agreement provides for certain rights relating to the registration of their shares of common stock issuable upon conversion of their redeemable convertible preferred stock and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the Investors' Rights Agreement), all rights under this agreement terminated upon closing of our initial public offering. The registration rights have continued following our initial public offering and will terminate five years after the closing of our initial public offering or earlier for certain holders. See the section titled "Description of Capital Stock—Registration Rights" for more information regarding these registration rights our initial public offering.

Voting Agreement

We entered into a voting agreement in July 2014, as last amended and restated in July 2023 (the Voting Agreement), with the holders of our redeemable convertible preferred stock and certain holders of our common stock, including the holders of more than 5% of our capital stock listed above as well as entities with which certain of our directors are affiliated, pursuant to which the following directors were each elected to serve as members on our board of directors and, as of the date of this Annual Report, continue to so serve: Brian Liu, M.D., Simone Song, James J. Mulé, IPh.D., Arthur Kuan, Leonard Post, Ph.D. and Victor Tong, Jr. Pursuant to the Voting Agreement, Mr. Kuan, as our Chief Executive Officer, serves on our board of directors as the CEO director. Mr. Tong was selected to serve on our board of directors as representative of the holders of our common stock and holders of our redeemable convertible preferred stock, voting together as a single class on an as-converted basis, Dr. Post was selected to serve on our board of directors as representative of the holders of our common stock, Mr. Kuan was selected to serve on our board of directors as representative of the holders of our Series A-1 redeemable convertible preferred stock, Dr. Mulé was selected to serve on our board of directors as representative of the holders of our Series B redeemable convertible preferred stock, Ms. Song was selected to serve on our board of directors as representative of the holders of our Series C redeemable convertible preferred stock, and Dr. Liu was selected to serve on our board of directors as a representative of the holders of our Series E redeemable convertible preferred stock.

The Voting Agreement terminated upon the closing of our initial public offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors is described in more detail in the section titled "Board Composition and Election of Directors" within Item 10 of Part III of this Annual Report.

Right of Refusal and Co-Sale Agreement

We entered into a right of first refusal and co-sale agreement in July 2014, as last amended and restated in July 2023 (the ROFR Agreement), with holders of our common stock affiliated with our executive officers, which entities are referred to in the ROFR Agreement as key holders, and certain other holders of redeemable convertible preferred stock, including the holders of more than 5% of our capital stock listed above. Pursuant to the ROFR Agreement, we have a right of first refusal on certain transfers of our shares by the key holders, holders of our redeemable convertible preferred stock have a secondary right of first refusal on such transfers, and such redeemable convertible preferred stockholders have a right of co-sale in respect of such transfers. The ROFR Agreement terminated upon the completion of our initial public offering.

Consulting Agreement with Danforth Advisors

On March 16, 2021, we entered into a consulting agreement with Danforth Advisors, LLC (Danforth) to provide us with resources to assist with our day-to-day finance and accounting functions. Services provided under the agreement with Danforth are billed at hourly rates. Stephen DiPalma, a managing director at Danforth, served as our Chief Financial Officer on a part-time basis through January 2024 and was compensated through his position at Danforth. Mr. DiPalma will continue to provide us consulting services through our agreement with Danforth. The agreement does not have a specified term and can be terminated without cause upon 30 days' notice by either party. During the years ended December 31, 2023, 2022 and 2021, we made payments to Danforth for such services of $372,824, $38,392 and $57,875, respectively.

Consulting Agreement with Lion Healthcare Strategies

On April 15, 2021, we entered into a consulting agreement with Lion Healthcare Strategies to provide us with corporate and strategic consulting services. Services provided under the agreement with Lion Healthcare Strategies are billed at daily or hourly rates. Mr. Bellete is the sole owner of Lion Healthcare Strategies, served as Chief Executive Officer of Lion Healthcare Strategies, from April 2021 to August 2023, and has served as our President and Chief Operating Officer since July 2023. The agreement was terminated when Mr. Bellete joined our company. During the years ended December 31, 2023, 2022 and 2021, we made payments to Lion Healthcare Strategies for such services of $357,908, $433,269 and $204,000 respectively.

Participation in our Initial Public Offering

In January 2024, beneficial owners of more than 5% of our capital stock and their affiliates participated in our initial public offering. Foresite Capital, TCG Crossover, Decheng Capital Global, Longitude Capital, and Simone Hong Fang each purchased approximately $15.7 million, $15.2 million, $15.2 million, $9.5 million and $5.0 million, respectively, of shares of our common stock in our initial public offering at the initial public offering price of $19.00 per share.

Director and Officer Indemnification

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us or will require us to indemnify each director (and in certain cases their related venture capital funds) and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, which became effective upon the closing of our initial public offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Item 14. Principal Accounting Fees and Services.

The following table summarizes the fees of Ernst & Young LLP, our independent registered public accounting firm, billed to us for each of the last two fiscal years for audit services and billed to us in each of the last two fiscal years for other services:

	Fiscal Years Ended December 31,	
Fee Category	**2023**	**2022**
Audit Fees[(1)]	$1,481,000	$265,000
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$1,481,000	$265,000

(1) Audit Fees consist of fees for the audit of our financial statements and the issuance of consents and comfort letters in connection with registration statements, including the filing of our registration statement on Form S-1 for our initial public offering.

Audit Committee Pre-Approval of Audit and Non-Audit Services

The Audit Committee has established a policy that all audit and permissible non-audit services provided by our independent registered public accounting firm will be pre-approved by the Audit Committee, and all such services were pre-approved in accordance with this policy during the fiscal year ended December 31, 2023. These services may include audit services, audit-related services, tax services and other services. The Audit Committee considers whether the provision of each non-audit service is compatible with maintaining the independence of our auditors. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

1. Financial Statements.

The financial statements of CG Oncology, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this Annual Report contained in Part II, Item 8. Financial Statements and Supplementary Data.

2. Finance Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits.

A list of exhibits is set forth on the Exhibit Index immediately preceding the signature page of this Annual Report and is incorporated herein by reference.

Item 16. Form 10-K Summary.

None.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	S-1/A	01/18/24	3.3	
3.2	Amended and Restated Bylaws	S-1	01/02/24	3.4	
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	01/18/24	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated July 28, 2023, as amended, by and among the Registrant and certain of its stockholders	S-1/A	01/18/24	4.2	
4.3	Description of Registered Securities				X
10.1#	CG Oncology, Inc. 2015 Equity Incentive Plan, as amended, and form of stock grant agreement and form of stock option agreement thereunder	S-8	01/26/24	10.1	
10.2#	CG Oncology, Inc. 2022 Incentive Award Plan and form of stock option agreement, form of stock option agreement (early exercise) and form of restricted stock unit agreement thereunder	S-8	01/26/24	10.2	
10.3#	CG Oncology, Inc. 2024 Incentive Award Plan and form of stock option agreement and form of restricted stock unit agreement thereunder	S-8	01/26/24	10.3	
10.4#	CG Oncology, Inc. 2024 Employee Stock Purchase Plan	S-8	01/26/24	10.4	
10.5#	Non-Employee Director Compensation Program	S-1/A	01/18/24	10.5	
10.6†	Development and License Agreement, dated March 11, 2019, between the Lepu Biotech Co., Ltd. and the Registrant	S-1	01/02/24	10.6	
10.7†	License and Collaboration Agreement, dated March 26, 2020, between Kissei Pharmaceutical Co., Ltd. and the Registrant	S-1	01/02/24	10.7	
10.8†	First Amendment to the License and Collaboration Agreement, dated September 15, 2022, between Kissei Pharmaceutical Co., Ltd. and the Registrant	S-1	01/02/24	10.8	
10.9#	Form of Indemnification Agreement for Directors and Officers	S-1	01/02/24	10.9	
10.10#	Annual Bonus Plan	S-1	01/02/24	10.11	
10.13	Amended and Restated Employment Agreement, effective March 15, 2023, between Arthur Kuan and the Registrant	S-1	01/02/24	10.12	
10.14#	Amended and Restated Employment Agreement, effective December 13, 2023, between Arthur Kuan and the Registrant	S-1	01/02/24	10.13	
10.15#	Employment Agreement, effective July 9, 2023, between Ambaw Bellete and the Registrant	S-1	01/02/24	10.14	
10.16#	Amended and Restated Employment Agreement, effective December 13, 2023, between Ambaw Bellete and the Registrant	S-1	01/02/24	10.15	
10.17#	Employment Agreement, effective August 14, 2023, between Vijay Kasturi and the Registrant	S-1	01/02/24	10.16	

10.18#	Amended and Restated Employment Agreement, effective December 13, 2023, between Vijay Kasturi and the Registrant	S-1	01/02/24	10.17	
10.19#	Employment Agreement, effective January 16, 2024, between Corleen Roche and the Registrant	S-1/A	01/18/24	10.18	
23.1	Consent of Independent Registered Public Accounting Firm				X
31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
97#	Policy for the Recovery of Erroneously Awarded Compensation	S-1	01/02/24	10.10	

# Indicates management contract or compensatory plan.
* This certification is deemed not filed for purpose of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601 of Regulation S-K because it is both not material and is the type that the registrant treats as private or confidential.

SIGNATURES

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

CG ONCOLOGY, INC.

/s/ Arthur Kuan

Arthur Kuan
Chairman and Chief Executive Officer

Date: March 26, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Arthur Kuan **Arthur Kuan**	Chairman and Chief Executive Officer (principal executive officer)	March 26, 2024
/s/ Corleen Roche **Corleen Roche**	Chief Financial Officer (principal financial and accounting officer)	March 26, 2024
/s/ Susan Graf **Susan Graf**	Director	March 26, 2024
/s/ Brian Liu, M.D. **Brian Liu, M.D.**	Director	March 26, 2024
/s/ James J. Mulé, IPh.D. **James J. Mulé, IPh.D.**	Director	March 26, 2024
/s/ Leonard Post, Ph.D. **Leonard Post, Ph.D.**	Director	March 26, 2024
/s Simone Song **Simone Song**	Director	March 26, 2024
/s/ Victor Tong, Jr. **Victor Tong, Jr.**	Director	March 26, 2024

CG ONCOLOGY, INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of CG Oncology, Inc.

Opinion on the Financial Statements

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

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

Irvine, California
March 26, 2024

CG Oncology, Inc.

Balance Sheets
(In thousands, except share and per share amounts)

	December 31,	
Assets	**2023**	**2022**
Current assets:		
Cash and cash equivalents	$ 8,266	$ 88,143
Marketable securities	179,408	55,338
Prepaid expenses and other current assets	6,358	3,424
Other receivables	92	303
Total current assets	194,124	147,208
Property and equipment, net	69	86
Operating lease right-of-use assets	422	420
Other assets	19	33
Deferred offering costs	4,667	—
Total assets	$ 199,301	$ 147,747
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,242	$ 985
Success fee liability, current portion	352	—
Long-term debt, current portion	—	8,966
Operating lease liabilities, current portion	217	189
Accrued expenses and other current liabilities	10,443	5,289
Total current liabilities	14,254	15,429
Long-term debt	—	6,532
Success fee liability, net of current portion	13	352
Operating lease liabilities, net of current portion	244	257
Total liabilities	14,511	22,570
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock:		
Series A-1 redeemable convertible preferred stock, $0.0001 par value per share; 5,075,000 shares authorized, issued and outstanding as of December 31, 2023 and 2022; liquidation value of $3,570 as of December 31, 2023 and 2022	3,570	3,570
Series B redeemable convertible preferred stock, $0.0001 par value per share; 11,973,000 shares authorized, issued and outstanding as of December 31, 2023 and 2022; liquidation value of $10,000 as of December 31, 2023 and 2022	10,000	10,000
Series C redeemable convertible preferred stock, $0.0001 par value per share; 73,598,283 shares authorized, issued and outstanding as of December 31, 2023 and 2022; liquidation value of $22,000 as of December 31, 2023 and 2022	22,000	22,000
Series D redeemable convertible preferred stock, $0.0001 par value per share; 53,271,754 shares authorized, issued and outstanding as of December 31, 2023 and 2022; liquidation value of $47,300 as of December 31, 2023 and 2022	47,300	47,300
Series E redeemable convertible preferred stock, $0.0001 par value per share; 112,422,700 shares authorized, issued and outstanding as of December 31, 2023 and 2022; liquidation value of $120,000 as of December 31, 2023 and 2022	120,000	120,000
Series F redeemable convertible preferred stock, $0.0001 par value per share; 81,587,937 and zero shares issued and outstanding as of December 31, 2023 and 2022, respectively; liquidation value of $105,020 and zero as of December 31, 2023 and 2022, respectively	105,020	—
Stockholders' equity (deficit):		
Common stock, $0.001 par value per share; 493,530,000 and 393,500,000 shares authorized as of December 31, 2023 and 2022, respectively; 5,222,283 and 3,842,694 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Additional paid-in capital	6,842	3,642
Accumulated deficit	(129,942)	(81,335)
Total stockholders' deficit	(123,100)	(77,693)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 199,301	$ 147,747

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

CG Oncology, Inc.

Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Revenue:		
Research and collaboration revenue	$ 204	$ 191
Operating expenses:		
Research and development	45,752	29,029
General and administrative	9,901	6,408
Total operating expenses	55,653	35,437
Loss from operations	(55,449)	(35,246)
Other income (expense), net:		
Interest income (expense), net	6,904	(1)
Other (expense), net	(62)	(196)
Total other income (expense), net	6,842	(197)
Net loss and comprehensive loss	(48,607)	(35,443)
Deemed dividend on redeemable convertible preferred stock issuances	(410)	(474)
Cumulative redeemable convertible preferred stock dividends	(18,781)	(7,871)
Net loss attributable to common stockholders	$ (67,798)	$ (43,788)
Net loss per share attributable to common stockholders, basic and diluted	$ (15.65)	$ (11.71)
Weighted average shares of common stock outstanding, basic and diluted	4,330,933	3,740,892

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

CG Oncology, Inc.

Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share amounts)

	Series A-1 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C redeemable Convertible Preferred Stock		Series D Redeemable Convertible Preferred Stock		Series E Redeemable Convertible Preferred Stock		Series F Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance as of December 31, 2021	5,075,000	$ 3,570	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	—	$ —	—	$ —	3,713,579	$ —	$ 3,274	$ (45,892)	$ (42,618)
Issuance of Series E redeemable convertible preferred stock (inclusive of deemed dividend of $474k to accrete to redemption value)	—	—	—	—	—	—	—	—	112,422,700	120,000	—	—	—	—	(474)	—	(474)
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	129,115	—	166	—	166
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	676	—	676
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(35,443)	(35,443)
Balance as of December 31, 2022	5,075,000	$ 3,570	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	120,000 $ 0	—	—	3,842,694	$ —	$ 3,642	$ (81,335)	$ (77,693)
Issuance of Series F redeemable convertible preferred stock (inclusive of deemed dividend of $410k to accrete to redemption value)	—	—	—	—	—	—	—	—	—	—	81,587,937	105,020 $ 0	—	—	(410)	—	(410)
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	1,379,589	—	2,082	—	2,082
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,528	—	1,528
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(48,607)	(48,607)
Balance as of December 31, 2023	5,075,000	$ 3,570	11,973,000	$ 10,000	73,598,283	$ 22,000	53,271,754	$ 47,300	112,422,700	120,000 $ 0	81,587,937	105,020 $ 0	5,222,283	$ —	$ 6,842	$ (129,942)	$ (123,100)

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

CG Oncology, Inc.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2023	2022
Operating Activities		
Net loss	$ (48,607)	$ (35,443)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	17	15
Amortization of loan fees	3	12
Final payment amortization and loss on debt extinguishment	767	448
Success fee amortization	37	32
Stock-based compensation expense	1,528	676
(Accretion of discount) amortization of premium on short-term investments	(2,875)	—
Non-cash lease expense	12	17
Changes in operating assets and liabilities:		
Prepaid and current assets	(2,723)	1,073
Other assets	13	52
Accounts payable	2,012	(18)
Accrued expenses	4,137	3,332
Net cash used in operating activities	(45,679)	(29,804)
Investing Activities		
Purchase of short-term investments	(517,611)	(55,338)
Purchase of property and equipment	—	(14)
Proceeds from sales and maturities of short-term investments	396,416	—
Net cash used in investing activities	(121,195)	(55,352)
Financing Activities		
Proceeds from issuance of Series E redeemable convertible preferred stock, net of issuance costs	—	119,526
Proceeds from issuance of Series F redeemable convertible preferred stock, net of issuance costs	104,627	—
Payment of long-term debt	(16,291)	—
Deferred offering costs	(3,421)	—
Proceeds from exercise of common stock options	2,082	166
Net cash provided by financing activities	86,997	119,692
Net (decrease) increase in cash, cash equivalent and restricted cash	(79,877)	34,536
Cash, cash equivalents and restricted cash at beginning of year	88,143	53,607
Cash, cash equivalents and restricted cash at end of period	$ 8,266	$ 88,143
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ 376	$ 1,091
Cash paid for taxes	$ —	$ —
Supplemental Schedule of Noncash Investing and Financing Activities:		
Deferred offering costs, unpaid and accrued	$ 1,246	$ —
Operating lease right-of-use asset obtained in exchange for lease liabilities	$ 221	$ 474

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

CG Oncology, Inc.
Notes to Financial Statements

1. Description of Business and Basis of Presentation

Description of Business

Cold Genesys Inc. was incorporated in California in September 2010, reincorporated in Delaware in November 2017 and is headquartered in Irvine, California. Cold Genesys, Inc. changed its name to CG Oncology, Inc. (the Company), in March 2020. The Company is a late-stage clinical biopharmaceutical company focused on developing and commercializing its product candidate, cretostimogene, for patients with bladder cancer. The Company is at a clinical stage and does not project to generate significant revenues if and until the U.S. Food and Drug Administration (FDA) approves its primary asset, cretostimogene.

On January 11, 2024, the Company's board of directors approved a 1-for-9.535 reverse stock split of its issued and outstanding common stock and stock option awards which was effected on January 16, 2024. All issued and outstanding shares of common stock, stock option awards and per share data have been adjusted in these audited financial statements, on a retrospective basis, to reflect the reverse stock split for all periods presented. The par value of the common stock and preferred stock was not adjusted as a result of the reverse stock split.

The shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the conversion ratios for each series of the Company's Redeemable Convertible Preferred Stock, which automatically converted into shares of common stock upon the closing of the offering, were proportionally adjusted. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment in lieu of receiving fractional shares.

On January 29, 2024, the Company completed the closing of its initial public offering of 20,000,000 common shares at a price of $19.00 per share. Additionally, the underwriters exercised their option to purchase an additional 3,000,000 at a price of $19.00 per share. The common shares began trading on the Nasdaq Global Market on January 25, 2024, under the symbol "CGON". The Company received net proceeds of $400.4 million, after deducting discounts and commissions and other estimated offering expenses. In addition, as a result of its initial public offering, the Company's convertible preferred stock converted into common stock concurrently with the initial public offering.

Basis of Presentation

The accompanying financial statements are prepared in conformity with U.S. generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

Liquidity and Management's Plans

As of December 31, 2023, the Company had approximately $187.7 million of cash, cash equivalents and marketable securities and working capital of approximately $179.9 million. The revenue and income potential of the Company's business and market are unproven. The Company has experienced net losses and negative cash flows from operations since its inception and, as of December 31, 2023, the Company had an accumulated deficit of $129.9 million. During the year ended December 31, 2023, the Company incurred a net loss of $48.6 million and negative cash flows from operations of $45.7 million. The Company will continue to incur significant costs and expenses related to its ongoing operations until it successfully develops, obtains regulatory approval and gains market acceptance of cretostimogene and achieves a level of revenues adequate to support the Company's operations.

From inception to December 31, 2023, the Company has funded its operations through the issuance of shares of its redeemable convertible preferred stock and previously outstanding term debt. The Company believes that its current capital resources, which consist of cash, cash equivalents and marketable securities, will be sufficient to fund operations through at least the next twelve months from the date the accompanying financial statements are issued

based on its expected cash needs. As the Company continues to pursue its business plan, it expects to finance its operations through equity offerings, debt financings, or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. However, there can be no assurance that any additional financing or strategic arrangements will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it may be necessary to significantly reduce its scope of operations to reduce the current rate of spending through actions such as reductions in staff and the need to delay, limit, reduce or terminate its product development or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself, which could have a material adverse effect on the Company's business, results of operations or financial condition.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures in the accompanying notes. The Company bases its estimates, assumptions and judgments on historical experience when available and on various factors that it believes to be reasonable under the circumstances as of the date of the accompanying financial statements including the fair value of common stock, stock-based compensation expense, accrued expenses, lease accounting, and the recoverability of the Company's net deferred tax assets and related valuation allowance. In addition, other factors may affect estimates, including the expected business and operational changes, the sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Actual results could differ materially from the estimates and assumptions used in the preparation of the accompanying financial statements under different assumptions or conditions.

Cash, Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments and instruments with original maturities of 90 days or less that can be liquidated without prior notice or penalty to be cash equivalents. Cash equivalents consisted primarily of demand deposit accounts, insurance deposits and short-term U.S. Treasury money market funds as of December 31, 2023 and 2022. Marketable securities represent fixed income securities which consists of U.S. Treasury bills with maturities greater than 90 days.

Concentration of Credit Risks

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions in the United States. These deposits are held in checking and money market accounts and may, from time to time, exceed the federally insured amounts. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant risk in its cash and cash equivalents. The primary objectives of the Company's investment portfolio are the preservation of capital and maintenance of liquidity.

The Company is subject to risks common to companies in the biopharmaceutical industry, including, but not limited to, risks related to the successful development and commercialization of product candidates, fluctuations in operating results and financial risks, the ability to successfully raise additional funds when needed, protection of proprietary rights and patent risks, patent litigation, compliance with government regulations, dependence on key personnel and collaboration partners, and competition from competing products in the marketplace.

Fair Value of Financial Instruments

The Company applies fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures. The Company's financial instruments consist principally of cash, cash equivalents, marketable securities, accounts payable and operating lease liabilities. Fair value is measured as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market

participants at the measurement date. A fair value measurement assumes that the transaction to sell the asset or transfer the liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

***Level* 1**—Observable inputs such as unadjusted quoted prices in active markets that are accessible at the measurement date for identical unrestricted assets or liabilities the Company has the ability to access;

***Level* 2**—Inputs (other than quoted prices included within Level 1) that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

***Level* 3**—Unobservable inputs that are significant to the fair value measurement and reflect the reporting entity's use of significant management judgment and assumptions when there is little or no market data. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment. To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. The Company reviews the fair value hierarchy classification at each reporting date. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value measurement hierarchy during the years presented.

Comprehensive Loss

There were no differences between net loss and comprehensive loss presented in the statements of operations for the years ended December 31, 2023 and 2022.

Property and Equipment, Net

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated over five years, which equals the estimated useful lives of the respective assets.

The initial cost of property and equipment consists of its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use. Expenditures incurred after the assets have been put into operation, such as repairs and maintenance, are charged to expense in the period in which the costs are incurred. Major replacements, improvements, and additions are capitalized in accordance with Company policy.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist of property and equipment and operating lease right-of-use assets, for impairment at least annually and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If the asset is considered to be impaired, the amount of any impairment is measured as the difference between the carrying value

and the fair value of the impaired asset. The Company recognized no impairment losses for the years ended December 31, 2023 and 2022.

Deferred Offering Costs

The Company capitalizes as deferred offering costs all direct and incremental legal, professional, accounting and other third-party fees incurred in connection with the Company's initial public offering (IPO). The deferred offering costs will be offset against the IPO proceeds upon the consummation of an offering. As of December 31, 2023 and 2022, respectively, the Company had $4.7 million and zero in deferred offering costs, of which $0.2 million were in accounts payable and $1.0 million were in accrued expenses.

Leases

Lease right-of-use assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized when the Company takes possession of the leased property (the Commencement Date) based on the present value of lease payments over the lease term. At the inception of a contract, the Company determines whether the arrangement is or contains a lease based on the facts and circumstances present. The Company had no finance leases as of December 31, 2023 and 2022.

Operating lease right-of-use assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The lease terms used to calculate the right-of-use asset and related lease liability include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The Company elects the practical expedient to exclude short-term agreements of less than 12 months from capitalization. The Company enters into various operating leases for office space. The leases expire at various dates, have various options to renew, and may contain escalation provisions.

Rent expense on cancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning on the Commencement Date. The difference between rent expense and rent paid is accounted for as a component of operating lease right-of-use assets on the accompanying balance sheets. Landlord improvement allowances and other such lease incentives are recorded as property and equipment and as a reduction of the right-of-use leased assets and are amortized on a straight-line basis as a reduction to operating lease costs. The key estimates for the Company's leases include the incremental borrowing rate used to determine the present value of lease payments and the lease term. The Company's leases generally do not include an implicit rate. Management determines the incremental borrowing rate based on the information available at lease commencement.

Operating lease right-of-use assets are initially measured at cost, which comprises the initial amount of the 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. Operating lease right-of-use assets are subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Operating lease liabilities are initially measured at the present value of the unpaid lease payments at the lease commencement date.

Research and Collaboration Revenue

The Company entered into development and license agreements with Lepu Biotech Co., Ltd. (Lepu) and Kissei Pharmaceutical Co., Ltd. (Kissei), collectively referred to as the License and Collaboration Agreements. See Note 6 for a description of the License and Collaboration Agreements.

At contract inception, the Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities and therefore within the scope of ASC 808, *Collaborative Arrangements* (ASC 808). This assessment is performed throughout the

life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple units of account, the Company first determines which components of the collaboration are deemed to be within the scope of ASC 808 and which components of the collaboration are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue Recognitio*n (ASC 606).

For units of account of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election. The Company evaluates the income statement classification for presentation of amounts due from or owed to other participants associated with multiple activities in a collaboration arrangement based on the nature of each separate activity.

For units of account accounted within scope of ASC 606, to determine the appropriate amount of revenue to be recognized for the arrangements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company's performance obligations under the terms of these agreements include a license grant, research and development services or customer options, depending on the terms of the License and Collaboration Agreement. Payments to the Company include a non-refundable upfront payment, payments based upon the achievement of development and commercial milestones, and royalties on product sales under the License and Collaboration agreements.

Development milestones

The License and Collaboration Agreements include milestone payments that are triggered by the achievement of development milestones. These milestone payments represent variable consideration that are not initially recognized within the transaction price. Revenue from milestones will be recognized at the time the specified milestone events have been achieved.

Sales milestones and royalty payments

The License and Collaboration Agreements also include certain sales-based milestone and royalty payments upon successful commercialization of a licensed product. In accordance with ASC 606, the Company recognizes revenue from sales-based milestone and royalty payments at the later of: (i) the occurrence of the subsequent sale; or (ii) the performance obligation to which some or all of the sales-based milestone or royalty payments has been allocated or has been satisfied. The Company anticipates recognizing these milestones and royalty payments if and when subsequent sales are generated.

Research and Development Expenses

Research and development (R&D) expenses consist of costs incurred for R&D of its product candidate and are recorded to operating expenses when incurred. The Company's R&D expenses consist primarily of costs incurred in performing R&D activities, including personnel-related expenses such as salaries, stock-based compensation and benefits, as well as allocated facilities costs, dues and subscriptions and external costs of outside vendors engaged as contract research organization (CRO), contract manufacturers, consultants and other third parties to conduct and support our clinical trials and preclinical studies. The Company accrues expenses related to development activities performed by third parties based on an evaluation of services received and efforts expended pursuant to the terms of the contractual arrangements. Payments under some of these contracts depend on clinical trial milestones. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of expenses. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual or prepaid expense

accordingly. Costs to acquire technologies to be used in R&D that have not reached technological feasibility and have no alternative future use are also expensed as incurred.

Stock-Based Compensation

As of December 31, 2023 and 2022, the Company had two stock-based compensation plans, the 2015 Equity Incentive Plan (the 2015 Plan) and 2022 Incentive Award Plan (the 2022 Plan), which are more fully described in Note 9.

The Company periodically grants equity-based payment awards in the form of stock options to employees, directors and non-employees and records stock-based compensation expenses for awards of stock-based payments based on their estimated fair value at the grant date. The Company recognizes stock-based compensation expense for all equity-based payments, including stock options. Stock-based compensation costs are calculated based on the estimated fair value of the underlying option using the Black-Scholes option pricing model on the date of grant for stock options and are recognized as expense in the accompanying statement of operations and comprehensive loss on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related input assumptions requires judgment, including estimating the fair value of the Company's common stock, stock price volatility, and expected term.

Given the absence of a public trading market, the fair value of the Company's common stock is determined by the Company's Board of Directors (the Board) at the time of each option grant by considering a number of objective and subjective factors. These factors include the valuation of a select group of public peer companies within the industry that focus on biotechnology that the Board believes is comparable to the Company's operations; operating and financial performance; the lack of liquidity of the common stock and trends in the broader economy and medical device industry also impact the determination of the fair value of the common stock. In addition, the Company regularly engages a third-party valuation specialist to assist with estimates related to the valuation of the Company's common stock;

- The risk-free interest rate used is based on the published U.S. Department of Treasury interest rates in effect at the time of stock option grant for zero coupon U.S. Treasury notes with maturities approximating each grant's expected term;
- The dividend yield is zero as the Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future;
- The expected term for options granted is calculated using the simplified method and represents the average time that options are expected to be outstanding based on the mid-point between the vesting date and the end of the contractual term of the award;
- Expected volatility is derived from the historical volatilities of a select group of comparable peer companies, for a look-back period commensurate with the expected term of the stock options, as the Company has no trading history of common stock.

The Company recognizes forfeitures related to stock-based compensation awards as they occur.

The Company classifies stock-based compensation expense in the statement of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* (ASC 740). ASC 740 requires the use of the asset and liability method of accounting for income taxes. The current or deferred tax consequences of a transaction are measured by applying the provisions of enacted tax laws to determine the amount of taxes payable currently or in future years. Deferred tax assets and liabilities are determined based on the difference between the financial statements and tax basis of assets and liabilities and expected future tax consequences of events that have been included in the financial statements or tax returns using enacted tax rates in effect for the year in which

the differences are expected to reverse. Under this method, a valuation allowance is used to offset deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. Management annually evaluates the recoverability of deferred taxes and the adequacy of the valuation allowance. See Note 10 for additional information.

The Company follows the provisions of ASC 740 relative to accounting for uncertain tax positions. These provisions provide guidance on the recognition, de-recognition and measurement of potential tax benefits associated with tax positions. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As applicable, the Company recognizes accrued penalties and interest related to unrecognized tax benefits in the provision for income taxes.

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. The Company assesses the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history and reliability of forecasting.

The Company is required to file federal and state income tax returns in the U.S. The preparation of state tax returns requires the Company to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid by the Company.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

The Company follows the accounting guidance on accounting for uncertainty in income taxes. The guidance prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return.

Classification of Redeemable Convertible Preferred Stock

Classification of the Company's Series A-1, B, C, D, E and F redeemable convertible preferred stock is being treated as mezzanine equity and not as part of stockholders' deficit because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, are not solely within the control of the Company and would require the redemption of the then-outstanding redeemable convertible preferred stock. In addition, all of the Company's redeemable convertible preferred stock are redeemable with the passage of time on or after July 28, 2028, by class and if requested by a requisite majority of each class. See Note 7 for additional information.

The carrying values of the Series A-1, B, C, D, E and F redeemable convertible preferred stock are reported at their respective redemption values.

Net Loss Per Share Attributable to Common Stockholders

The Company determined all of its redeemable convertible preferred stock qualifies as participating securities, as defined in ASC 260, *Earnings per Share* (ASC 260) earnings with common stock. In accordance with ASC 260, a company is required to use the two-class method when computing net income (loss) per share when a company has securities that qualify as participating securities. The two-class method is an earnings allocation formula that determines net income (loss) per share for each class of common stock and participating security according to dividends declared (or accumulated) and participation rights in undistributed earnings. Under the two-class method, the net loss attributable to common stockholders is not allocated to the convertible preferred stock as the preferred stockholders do not have a contractual obligation to share in the Company's losses.

Segment and Geographic Information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) about which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is its Chief Executive Officer. The chief operating decision maker reviews consolidated operating results to make decisions about allocating resources and assessing performance for the entire company. The Company views its operations and manages its business as one operating segment. All of the Company's assets are located in the United States.

Recently Issued Accounting Standards

Accounting standards not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company's financial statements.

In November 2023, the FASB issued Accounting Standards Update 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (ASU 2023-07). The guidance includes the requirements that a public entity disclose, on an annual and interim basis, significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, the title and position of the chief operating decision maker, and an explanation of how the chief operating decision maker uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. The guidance also requires that a public entity that has a single reportable segment provide all the disclosures required by the guidance and all existing segment disclosures in ASC 280, Segment Reporting. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. A public entity should apply the amendments in the guidance retrospectively to all prior periods presented in the financial statements. Upon transition, the segment expense categories and amounts disclosed in the prior periods should be based on the significant segment expense categories identified and disclosed in the period of adoption. The Company is currently evaluating the impact that this guidance may have on its financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The guidance includes the requirement that public business entities, on an annual basis, disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5% of the amount computed by multiplying pretax income (or loss) by the applicable statutory income tax rate). It also requires that all entities disclose, on an annual basis, the amount of income taxes paid (net of refunds received) disaggregated by federal (national), state, and foreign taxes and the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid (net of refunds received) is equal to or greater than 5% of total income taxes paid (net of refunds received) and requires that all entities disclose income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) from continuing operations disaggregated by federal (national), state, and foreign. Lastly, the guidance eliminates the requirement for all entities to disclose the nature and estimate of the range of the reasonably possible change in the unrecognized tax benefits balance in the next 12 months or make a statement that an estimate of the range cannot be made. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The guidance

should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating the impact that this guidance may have on its financial statements.

3. Fair Value Measurements

The following tables present the financial instruments carried at fair value on a recurring basis as of December 31, 2023 and 2022 in accordance with the ASC 820, *Fair Value Measurement* (ASC 820) hierarchy (in thousands):

	Fair Value Measurements at December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 8,240	$ —	$ —	$ 8,240
Marketable securities	$ —	$ 179,408	$ —	$ 179,408
Liabilities				
Success fee liability	$ —	$ —	$ 365	$ 365

	Fair Value Measurements at December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 87,143	$ —	$ —	$ 87,143
Marketable securities	$ —	$ 55,338	$ —	$ 55,338
Liabilities				
Success fee liability	$ —	$ —	$ 352	$ 352

The Company's cash equivalents represent deposits in a short-term U.S. Treasury money market fund quoted in an active market and were classified as a Level 1 fair value measurement. Marketable securities represent fixed income securities (U.S. treasury bills) with original maturities greater than 90 days and were classified as a level 2 fair value measurement.

The success fee liability associated with the Loan and Security Agreement (the Loan Agreement) the Company entered into in January 2021 was classified as a Level 3 fair value measurement, due to the use of unobservable inputs. See Note 11 for additional information on the Loan Agreement and success fee.

There were no transfers between Level 1 and Level 2 of the fair value hierarchy during the years ended December 31, 2023 and 2022.

The following table provides a summary of the changes in the Company's Level 3 fair value measurement (in thousands):

Balance, December 31, 2021	$ 351
Increase in fair value of success fee recorded in earnings	1
Balance, December 31, 2022	$ 352
Increase in fair value of success fee recorded in earnings	13
Balance, December 31, 2023	$ 365

4. Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities for the years ended December 31, 2023 and 2022 were as follows (in thousands):

	December 31,	
	2023	2022
External research and development expenses	$ 6,164	$ 3,136
Personnel-related expenses	2,822	1,833
Professional fees	341	147
Deferred offering costs	1,017	—
Other	99	173
Total accrued expenses and other current liabilities	$ 10,443	$ 5,289

5. Commitments and Contingencies

Operating Leases

On January 1, 2019, the Company adopted ASC 842, *Leases*. As of December 31, 2023 and 2022, the Company had two operating leases, in which the Company is the lessee for office space. As of December 31, 2023, the lease terms were through 2025 and 2026. The Company had no finance leases as of December 31, 2023 and 2022.

The components of lease expense for the years ended December 31, 2023 and 2022 were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Lease cost		
Operating lease cost	$ 232	$ 173
Total lease cost	$ 232	$ 173
Other information		
Operating lease right-of-use asset obtained in exchange for new operating lease liabilities	$ 221	$ 474
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 219	$ 155
Weighted-average remaining lease term	2.15	2.45
Weighted-average discount rate	1.63%	1.63%

Maturities of lease liabilities as of December 31, 2023 were as follows (in thousands):

Year Ending December 31,	
2024	$ 223
2025	187
2026	59
Total lease payment	469
Less: amount representing imputed interest	(8)
Total future minimum lease obligations	$ 461

Legal Proceedings

A liability for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources is recorded in the financial statements if it is determined that it is probable that a loss has been incurred, and that the amount (or range) of the loss can be reasonably estimated.

On March 4, 2024, a complaint was filed against the Company in the Superior Court of the State of Delaware by ANI Pharmaceuticals, Inc. seeking a declaratory judgement that an assignment and technology transfer agreement between the Company and ANI, dated November 15, 2010, obligates the Company to pay ANI a royalty on certain "net sales" of cretostimogene. The Company disputes the allegations and intends to vigorously defend the matter.

Indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with officers and members of the Board that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. As of December 31, 2023 and 2022, the Company had not experienced any losses related to these indemnification obligations, and no claims with respect thereto were outstanding.

6. License and Collaboration Agreements

Lepu Biotech Co., Ltd.

In March 2019, the Company entered into a development and license agreement with Lepu for cretostimogene (the Lepu License Agreement). Under the terms of the Lepu License Agreement, the Company granted to Lepu an exclusive license to develop, manufacture and commercialize cretostimogene and/or DDM to treat and/or prevent cancer in mainland China, including Hong Kong and Macau (the Lepu Territory). The Company is obligated to use commercially reasonable efforts to supply Lepu with its requirements of cretostimogene and DDM for its development activities at Lepu's cost and to periodically provide Lepu with manufacturing documentation and, at Lepu's cost, reasonably requested assistance related to the manufacture of clinical and, if applicable, commercial supplies of cretostimogene and DDM. The Company determined that control of the license was transferred to Lepu on March 2019 upon execution of the contract.

Lepu paid to the Company a one-time upfront payment of $4.5 million and is obligated to make regulatory milestone payments of up to $2.5 million and commercial milestone payments of up to $57.5 million. The Company is entitled to receive a high single-digit royalty on net sales of cretostimogene and/or DDM sold in the Lepu Territory, subject to a specified reduction. Lepu's royalty obligations will expire upon termination of the Lepu License Agreement.

The Company assessed the Lepu License Agreement in accordance with ASC 606 and determined that the performance obligation is comprised solely of the license grant to Lepu. The Company determined the transaction price was $4.5 million and recorded the entire amount upon transfer of control of the functional intellectual property license rights in 2019. The Company evaluated the provision of manufacturing activities related to clinical and commercial supply of the licensed products and concluded that the manufacturing activities were not performance obligations as the terms do not provide a material right to Lepu.

Future milestone payments are fully contingent as the risk of significant revenue reversal will only be resolved depending on future regulatory approval and sales level outcomes. The Company will re-evaluate the likelihood of achieving future milestones at the end of each reporting period.

The sales-based royalty fee is considered variable consideration and will be recognized as revenue as such sales occur. The sales-based royalty fee qualifies for the royalty constraint exception and does not require an estimate of the future transaction price.

For the years ended December 31, 2023 and 2022, less than $0.1 million and zero in development revenue were recorded.

Kissei Pharmaceutical Co., Ltd.

In March 2020, and amended as of September 2022, the Company entered into a license and collaboration agreement with Kissei (the Kissei License Agreement). Under the terms of the Kissei License Agreement, the Company granted to Kissei an exclusive license to certain intellectual property rights in Bangladesh, Bhutan, Brunei, Cambodia, India, Indonesia, Japan, South Korea, Laos, Malaysia, Myanmar, Nepal, Pakistan, Palau, Philippines, Singapore, Sri Lanka, Taiwan, Thailand and Vietnam (the Kissei Territory), for Kissei to develop and commercialize, but not manufacture, cretostimogene in combination with DDM (the Licensed Product) for all uses in oncology indications for which marketing approval is being sought. Under the Kissei Agreement, the Company and Kissei agree to use commercially reasonable efforts to collaborate on clinical development activities in the Kissei Territory and each party is responsible for conducting the applicable activities pursuant to an agreed development plan. Kissei is responsible for the costs of developing the Licensed Product in the Kissei Territory, and the Company is responsible for the costs of developing the Licensed Product outside the Kissei Territory (Global Development), provided that Kissei is responsible for a low-double digit percentage and the Company is responsible for a high-double digit percentage of the cost of development activities that cannot be attributed solely to the Kissei Territory or outside the Kissei Territory. The Company is obligated to supply and Kissei will exclusively purchase its clinical and commercial requirements of Licensed Product from the Company. Kissei is responsible for commercializing the Licensed Product in the Kissei Territory and is obligated to use commercially reasonable efforts to seek regulatory approval for and commercialize at least one Licensed Product in a specified indication. Until a certain period of time has passed after the first regulatory approval of the Licensed Product, the Company is prohibited from commercializing certain competing products worldwide and Kissei is prohibited from researching, developing or commercializing certain competing products worldwide.

Under the terms of the Kissei License Agreement, the Company received a $10.0 million one-time upfront payment and, in connection with entry into this agreement, Kissei purchased $30.0 million worth of Series D redeemable convertible preferred stock as part of the Company's Series D financing. Kissei is obligated to make development and regulatory milestone payments to the Company of up to $33.0 million and commercial milestone payments of up to $67.0 million. The Company has agreed to pay Kissei a royalty on net sales of Licensed Product outside the Kissei Territory and outside the Lepu Territory (as described above), including on any U.S. sales, in a low-single digit percentage, subject to certain capped reductions. We are entitled to receive a royalty on net sales of Licensed Product in the Kissei Territory in the mid-twenties percentage, subject to certain capped reductions. Also, Kissei has the right to offset the royalty payments due to the Company with respect to the cost for the supply of Licensed Product sold by the Company to Kissei, and to indefinitely carryforward credits for any excess supply amounts paid over royalty amounts owed in a given quarter. The Company is entitled to receive a specified minimum percentage of royalties on net sales of a given Licensed Product in a given country and a given quarter, unless, if for such Licensed Product in such country and such quarter, Kissei has taken the maximum allowable reductions and the ratio of the cost for the supply of Licensed Product to the sales price for Licensed Product exceeds a low-double digit percentage threshold, then the Company shall receive no royalties on the net sales of such Licensed Product in such country and such quarter. Kissei's and the Company's royalty obligations will expire on a Licensed Product-by-Licensed Product and country-by-country basis on the later of twelve years from the date of first commercial sale of such Licensed Product in such country or when there is no longer a valid patent claim covering such Licensed Product in such country.

The Kissei Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country basis when there is no remaining royalty or milestone payment obligation due to a party with respect to such Licensed Product in such country. Following expiration of the Kissei Agreement in its entirety, the licenses the Company granted to Kissei will become non-exclusive, fully-paid royalty-free and irrevocable and Kissei will have the right to negotiate directly with our product suppliers for the direct supply of Licensed Product to Kissei. The Kissei Agreement may be terminated either by Kissei or by the Company in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, insolvency or similar circumstances. In addition, the Company have the right to terminate the Kissei Agreement in the event that Kissei commences a legal action challenging the validity, enforceability or scope of any licensed patents under the Kissei Agreement. Kissei may terminate the Kissei Agreement at will upon specified written notice. Additionally, Kissei may terminate the Kissei Agreement for our willful and malicious misconduct that results in substantial and irreparable harm to the commercial value of the Licensed Products in the Kissei Territory and upon any such termination, the licenses the Company granted to Kissei will become royalty-free and fully paid-up and Kissei will have the right to negotiate directly with our contract manufacturing organizations for the supply of Licensed Product. Upon termination of the Kissei Agreement for any other reason all rights and licenses granted to Kissei to develop and commercialize the

product under the Kissei Agreement will terminate, subject to certain rights to sell existing inventory of Licensed Products by Kissei and its sublicensees. Upon termination of the Kissei Agreement for Kissei's breach, any sublicenses granted by Kissei may, upon the Company's discretion, continue.

The Company evaluated the Kissei Agreement to determine whether it is a collaborative arrangement in the scope of ASC 808. The Company concluded the Kissei Agreement is a collaborative agreement under ASC 808, as the Kissei Agreement involves a joint operating activity, each party is an active participant in the activities related to the Kissei Agreement, and both parties are exposed to significant risks and rewards dependent upon the commercial success of the activities related to the Kissei Agreement.

The Company determined the Kissei Agreement contained two material components: (i) an exclusive license granted to Kissei to certain intellectual property rights in the Kissei Territory, for Kissei to develop and commercialize, but not manufacture, the Licensed Product for all uses in oncology; and (ii) the parties' participation in the Global Development of the Licensed Product. The Company used the criteria specified in ASC 606 to determine which of the components of the Kissei Agreement are performance obligations with a customer and concluded Kissei is the Company's customer for the license and related activities in the Kissei Territory under ASC 606. The Global Development activities under the agreement does not present a transaction with a customer and the payments received by the Company for Global Development activities, including manufacturing, will be accounted for as a reduction of related expenses.

The Company evaluated the Kissei Territory specific license and related activities under ASC 606, as these transactions are considered transactions with a customer, and identified two material promises at the outset of the Kissei License Agreement, which consists of the following: (1) the exclusive license and (2) the manufacturing activities related to development and commercial supply of the Licensed Product in the Kissei Territory. The Company further evaluated the material promise associated with manufacturing activities related to development and commercial supply of the Licensed Products in the Kissei Territory. Given Kissei is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company, the Company concluded, for the purpose of ASC 606, the provision of manufacturing activities related to development and commercial supply of the Licensed Product in the Kissei Territory was an option but not a performance obligation of the Company at the inception of the Kissei Agreement and will be accounted for if and when exercised. The Company also concluded there is no separate material right in connection with the development and commercial supply of the licensed product, as the expected pricing was not issued at a significant and incremental discount. Therefore, the manufacturing activities were excluded as performance obligation at the outset of the arrangement.

The Company evaluated the license under ASC 606 and concluded the license is a functional intellectual property license. The Company determined Kissei benefited from the license at the time of grant and, therefore, the related performance obligation was satisfied at a point in time. Additionally, the Company is entitled to development and regulatory milestones as well as sales milestones and royalties from Kissei upon future sales of the Licensed Product in the Kissei Territory. Future milestone payments are fully contingent as the risk of significant reversal will only be resolved depending on future development milestones, regulatory approval and sales level outcomes. The Company re-evaluates the likelihood of achieving future milestones at the end of each reporting period. The royalties are considered variable consideration and will be recognized as revenue as such sales occur. The sales-based royalties qualify for the royalty constrain exception and do not require an estimate of the future transaction price.

As the sale of $30.0 million of the Company's Series D redeemable convertible preferred stock and the Kissei License Agreement were entered into concurrently and negotiated as a package with a single commercial objective, the Company accounted for the two agreements as a single arrangement for accounting purposes. The total upfront payments of $40.0 million were comprised of $30.0 million attributed to the Series D redeemable convertible preferred stock sold to Kissei and $10.0 million attributed to the functional intellectual property license granted to Kissei. The Company determined that the sale of the Series D redeemable convertible preferred stock of $30.0 million was at fair value and did not include a premium or discount. As a result, $10.0 million of the total upfront payments was allocated to the transaction price of the exclusive license.

For the purposes of ASC 606, the transaction price of the Kissei Agreement as of the outset of the arrangement was determined to be $10.0 million, which consisted of the one-time upfront payment. The other potential milestone payments the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were

fully constrained based on the probability of achievement. The Company satisfied the performance obligation upon delivery of the license and recognized the upfront payment of $10.0 million as revenue during the year ended December 31, 2020.

During the year ended December 31, 2021, the Company recognized milestone revenue of $10 million for cash consideration received associated with an achieved development milestone and $0.4 million in development income related to the Kissei License Agreement.

During the years ended December 31, 2023 and 2022, the Company recorded $0.2 million in development income related to the Kissei License Agreement.

7. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock consisted of the following as of December 31, 2023 (in thousands, except share amounts):

December 31, 2023	Authorized Shares	Shares Issued and Outstanding	Liquidation & Carrying Value	Common Stock Issuable Upon Conversion
Series A-1	5,075,000	5,075,000	$ 3,570	1,252,438
Series B	11,973,000	11,973,000	$ 10,000	3,508,584
Series C	73,598,283	73,598,283	$ 22,000	7,718,740
Series D	53,271,754	53,271,754	$ 47,300	5,586,959
Series E	112,422,700	112,422,700	$ 120,000	11,790,523
Series F	81,587,937	81,587,937	$ 105,020	8,556,669

Series F Redeemable Convertible Preferred Stock

In 2023, the Company entered into a securities purchase agreement (Series F Agreement) with certain investors to sell shares of Series F redeemable convertible preferred stock (Series F) at $1.2872 per share. In July 2023, the Company issued 81,587,937 shares of Series F redeemable convertible preferred stock to existing and new investors at $1.2872 per share for gross cash proceeds of $105.0 million, less issuance costs of $0.4 million, resulting in net proceeds of $104.6 million.

Rights, Preferences, Privileges and Restrictions

Voting Rights

Each preferred stockholder is entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of preferred stock held by such holder are convertible at the time of such vote. All preferred stockholders are entitled to vote on all matters upon which holders of common stock have the right to vote, other than matters that must by law be voted by class or series vote.

Conversion Rights

Each share of redeemable convertible preferred stock is convertible at the option of the holder at any time into a share of common stock. Each share of convertible preferred stock is convertible into that number of common shares as is determined by dividing the applicable Initial Purchase Price (the Initial Purchase Price) of such share by the applicable conversion price. The conversion rate is subject to adjustment upon the occurrence of certain events, including diluting issues of shares, stock splits, stock combinations, certain dividends and distributions, a merger and a reorganization. The conversion rates for each series of redeemable convertible preferred stock as of December 31, 2023 are as follows: Series A-1 1:4.05, Series B 1:3.412, and Series C, D, E, and F 1:9.535.

All shares of the redeemable convertible preferred stock shall automatically be converted into shares of common stock, based on the then-effective applicable conversion rate (i) upon the closing of the sale of shares of common stock

to the public at a price of at least $1.33 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, covering the offer and sale of common stock for the account of the Company (1) which results in at least $100.0 million of gross proceeds to the Company and (2) in which the pre-money valuation of the Company immediately prior to such public offering is at least $700.0 million or (ii) upon the written consent of the holders of at least 75% of the then-outstanding shares of convertible preferred stock voting together as a single class and not as separate series, and on an as-converted to common stock basis.

Dividend Rights

Holders of Series F Preferred Stock shall be entitled to receive, prior and in preference to any other class or series of capital stock, cumulative cash dividends, when, as and if declared by the Board, out of any funds that are legally available, at the rate of 8% of the Series F Initial Purchase Price of $1.2872 per annum on each outstanding share of Series F Preferred Stock, subject to adjustment for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares.

Following the issuance and distribution of dividends to holders of Series F Preferred Stock, holders of Series E Preferred Stock shall be entitled to receive, prior and in preference to the holders of Series D Preferred Stock and Series C Preferred Stock (together, the Senior Preferred Stock), Series B Preferred Stock, Series A-1 Preferred Stock and common stock, cumulative cash dividends, when, as and if declared by board of directors, out of any funds that are legally available, at the rate of 8% of the Series E Initial Purchase Price per annum on each outstanding share of Series E Preferred Stock, subject to adjustment for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares.

Following the issuance and distribution of dividends to holders of Series F Preferred Stock and Series E Preferred Stock, holders of Series D Preferred Stock and Series C Preferred Stock (together, the Senior Preferred Stock) shall be entitled to receive, on a pari passu basis and prior and in preference to the holders of Series B Preferred Stock, Series A-1 Preferred Stock and common stock, cumulative cash dividends, when, as and if declared by the Board, out of any funds that are legally available, at the rate of (i) with respect to the Series E Preferred Stock, 8% of the Series E Initial Purchase Price per annum on each outstanding share of Series E Preferred Stock, subject to adjustment for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares (ii) with respect to the Series D Preferred Stock, 8% of the Series D Initial Purchase Price per annum on each outstanding share of Series D Preferred Stock, subject to adjustment for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares and (iii) with respect to the Series C Preferred Stock, 8% of the Series C Initial Purchase Price per annum on each outstanding share of Series C Preferred Stock, subject to adjustment for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares.

Following the issuance and distribution of dividends to holders of Series F Preferred Stock, Series E Preferred Stock and Senior Preferred Stock, holders of Series B Preferred Stock and Series A-1 Preferred Stock shall be entitled to receive, on a pari passu basis and prior and in preference to the holders of common stock, noncumulative cash dividends, when, as and if declared by the Board of Directors, out of any funds that are legally available, at the rate of (i) with respect to the Series B Preferred Stock, 8% of the Series B Initial Purchase Price per annum on each outstanding share of Series B Preferred Stock, subject to adjustment for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares and (ii) with respect to the Series Preferred Stock, 8% of the Series Initial Purchase Price per annum on each outstanding share of Series Preferred Stock, subject to adjustment for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares.

No distributions shall be made with respect to the common stock unless dividends on the redeemable convertible preferred stock have been declared and all declared dividends on the redeemable convertible preferred stock have been paid or set aside for payment to the redeemable convertible preferred stockholders. The right to receive dividends on shares of Series B Preferred Stock and Series A-1 Preferred Stock shall not be cumulative, and no right to dividends shall accrue to holders of Series B Preferred Stock and Series A-1 Preferred Stock by reason of the fact that dividends on said shares are not declared or paid. Payment of any dividends to the holders of Series B Preferred Stock and

Series A-1 Preferred Stock shall be on a pro rata, pari passu basis in proportion to the dividend rate for the Series B Preferred Stock and Series A-1 Preferred Stock, as applicable.

After payment of the full amount of any dividends to holders of redeemable convertible preferred stock, any additional dividends shall be distributed among all holders of common stock and all holders of redeemable convertible preferred stock in proportion to the number of shares of common stock which would be held by each such holder if all such shares of redeemable convertible preferred stock were converted to common stock at the then-effective applicable conversion rate. The Company has not declared or paid any dividends for the year ended December 31, 2023 and 2022.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, or a deemed liquidation event of the Company (which includes certain mergers, acquisitions, and asset transfers), before any distribution or payment shall be made to the holders of common stock:

(i) The holders of Series F Preferred Stock shall be entitled to be paid out of the assets of the Company, prior and in preference to any distribution of the proceeds of such liquidation, dissolution or winding up to the holders of Series E Preferred Stock, Senior Preferred Stock, Series B Preferred Stock, Series A-1 Preferred Stock or common stock, an amount per share of Series F Preferred Stock equal to the Series F Initial Purchase Price, plus all declared but unpaid dividends on the Series E Preferred Stock, for each share of Series F Preferred Stock then held.

(ii) Following the distribution pursuant to holders of Series F Preferred Stock, the holders of Series E Preferred Stock shall be entitled to be paid out of the assets of the Company, prior and in preference to any distribution of the proceeds of such liquidation, dissolution or winding up to the holders of Senior Preferred Stock, Series B Preferred Stock, Series A-1 Preferred Stock or common stock, an amount per share of Series E Preferred Stock equal to the Series E Initial Purchase Price, plus all declared but unpaid dividends on the Series E Preferred Stock, for each share of Series E Preferred Stock then held.

(iii) Following the distribution pursuant to holders of Series F Preferred Stock and Series E Preferred Stock, the holders of each series of Senior Preferred Stock shall be entitled to be paid out of the assets of the Company, on a pari passu basis and prior and in preference to any distribution of the proceeds of such liquidation, dissolution or winding up to the holders of Series B Preferred Stock, Series A-1 Preferred Stock or common stock, (i) with respect to the Series D Preferred Stock, an amount per share of Series D Preferred Stock equal to the Series D Initial Purchase Price, plus all declared but unpaid dividends on the Series D Preferred Stock, for each share of Series D Preferred Stock then held and (ii) with respect to the Series C Preferred Stock, an amount per share of Series C Preferred Stock equal to the Series C Initial Purchase Price, plus all declared but unpaid dividends on the Series C Preferred Stock, for each share of Series C Preferred Stock then held

(iv) Following the distributions pursuant to holders of Series F Preferred Stock, Series E Preferred Stock and Senior Preferred Stock, the holders of Series B Preferred Stock and Series A-1 Preferred Stock shall be entitled to be paid out of the assets of this Corporation, on a pari passu basis (i) with respect to the Series B Preferred Stock, an amount per share of Series B Preferred Stock equal to the Series B Initial Purchase Price, plus all declared but unpaid dividends on the Series B Preferred Stock, for each share of Series B Preferred Stock then held; and (ii) with respect to the Series A-1 Preferred Stock, an amount per share of Series A-1 Preferred Stock equal to the Series A-1 Initial Purchase Price, plus all declared but unpaid dividends on the Series A-1 Preferred Stock, for each share of Series A-1 Preferred Stock then held by them.

(v) If, upon any such liquidation, dissolution or winding up, the assets of the Company shall be insufficient to make payment in full of the liquidation preferences described in (i), (ii), (iii) and (iv) above, then such assets shall be distributed in the following order of priority: (a) to the holders of Series F Preferred Stock in preference and ratably in proportion to the full amounts to which they would otherwise be respectively

entitled pursuant to in (i) above, (b) any remaining assets then to the holders of Series E Preferred Stock in preference and ratably in proportion to the full amounts to which they would otherwise be respectively entitled pursuant to (ii) above, (c) any remaining assets then to the holders of each series of Senior Preferred Stock in preference and ratably in proportion to the full amounts to which they would otherwise be respectively entitled pursuant to (iii) above, and (d) any remaining assets then to the holders of Series B Preferred Stock and Series A-1 Preferred Stock ratably in proportion to the full amounts to which they would otherwise be respectively entitled pursuant to (iv) above.

After the payment of the full liquidation preferences as set out above, the remaining assets of the Company legally available for distribution, if any, shall be distributed ratably to the holders of the common stock, Series F Preferred Stock on an as-converted to common stock basis, Series E Preferred Stock on an as-converted to common stock basis, Senior Preferred Stock on an as-converted to common stock basis and Series A-1 Preferred Stock on an as-converted to common stock basis; provided, however, that if the aggregate amount which a holder of a share of Series A-1 Preferred Stock is entitled to receive exceeds the sum of three times the Series A-1 Initial Purchase Price plus declared but unpaid dividends thereon, such holder of Series A-1 Preferred Stock shall cease participating in such distribution as to such Series A-1 Preferred Stock, and the balance shall be distributed ratably to the holders of common stock, Series F Preferred Stock on an as-converted to common stock basis, Series E Preferred Stock on an as-converted to common stock basis and Senior Preferred Stock on an as-converted to common stock basis.

Redemption Rights

At any time, following July 28, 2028, Convertible Preferred Shares are redeemable as follows:

(i) If requested in writing by holders of a majority of the then-outstanding shares of Series A-1 redeemable convertible preferred stock, all of the outstanding Series A-1 redeemable convertible preferred stock shall be redeemed by paying in cash in exchange for the shares of Series A-1 redeemable convertible preferred stock to be redeemed an amount equal to the Series A-1 Initial Purchase Price per share of Series A-1 redeemable convertible preferred stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), plus any and all declared but unpaid dividends with respect to such shares of Series A-1 redeemable convertible preferred stock

(ii) If requested in writing by holders of a majority of the then-outstanding shares of Series B redeemable convertible preferred stock, all of the outstanding Series B Preferred Stock shall be redeemed by paying in cash in exchange for the shares of Series B redeemable convertible preferred stock to be redeemed an amount equal to the Series B Initial Purchase Price per share of Series B redeemable convertible preferred stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), plus any and all declared but unpaid dividends with respect to such shares of Series B redeemable convertible preferred stock.

(iii) If requested in writing by holders of 66.67% of the then-outstanding shares of Series C redeemable convertible preferred stock and to the extent affirmatively elected by a holder not to redeem, shares of the outstanding Series C redeemable convertible preferred stock shall be redeemed by paying in cash in exchange for the shares of Series C redeemable convertible preferred stock to be redeemed an amount equal to the Series C Initial Purchase Price per share of Series C redeemable convertible preferred stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), plus any and all declared but unpaid dividends with respect to such shares of Series C redeemable convertible preferred stock.

(iv) If requested in writing by holders of a majority of the then-outstanding shares of Series D redeemable convertible preferred stock and to the extent affirmatively elected by a holder not to redeem, shares of the outstanding Series D redeemable convertible preferred stock shall be redeemed by paying in cash in exchange for the shares of Series D redeemable convertible preferred stock to be redeemed an amount equal to the Series D Initial Purchase Price per share of Series D redeemable convertible preferred stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to

such shares), plus any and all declared but unpaid dividends with respect to such shares of Series D redeemable convertible preferred stock.

(v) If requested in writing by holders of a majority of the then-outstanding shares of Series E redeemable convertible preferred stock and to the extent affirmatively elected by a holder not to redeem, all of the outstanding Series E Preferred Stock shall be redeemed by paying in cash in exchange for the shares of Series E Preferred Stock to be redeemed (other than those holders of Series E Preferred Stock that affirmatively choose to not participate in such redemption) an amount equal to: the Series E Initial Purchase Price per share of Series E Preferred Stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), plus any and all declared but unpaid dividends with respect to such shares of Series E Preferred Stock.

(vi) If requested in writing by holders of a majority of the then-outstanding shares of Series F redeemable convertible preferred stock and to the extent affirmatively elected by a holder not to redeem, all of the outstanding Series F Preferred Stock shall be redeemed by paying in cash in exchange for the shares of Series F Preferred Stock to be redeemed (other than those holders of Series F Preferred Stock that affirmatively choose to not participate in such redemption) an amount equal to: the Series F Initial Purchase Price per share of Series F Preferred Stock (as adjusted for any stock dividends, combinations, splits, recapitalizations and the like with respect to such shares), plus any and all declared but unpaid dividends with respect to such shares of Series F Preferred Stock.

8. Common Stock

The Company is authorized to issue up to 493,530,000 and 393,500,000 shares of common stock as of December 31, 2023 and 2022, respectively, of which 5,222,283 and 3,842,694 shares were issued and outstanding as of December 31, 2023 and 2022, respectively.

Voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights, preferences and privileges of the holders of the redeemable convertible preferred stock.

Voting

Each holder of outstanding shares of common stock shall be entitled to one vote in respect of each share. The holders of outstanding shares of common stock, voting together as a single class, shall be entitled to elect one director. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of a majority of the outstanding shares of common stock and preferred stock voting together as a single class.

Dividends

Subject to the payment in full of all preferential dividends to which the holders of the preferred stock are entitled, the holders of common stock shall be entitled to receive dividends out of funds legally available therefor at such times and in such amounts as the Board may determine in its sole discretion, with holders of preferred stock and common stock sharing pari passu in such dividends.

Liquidation Rights

After payment in full of all preferential amounts to which the holders of preferred stock are entitled upon any voluntary or involuntary liquidation, dissolution or winding-up of the Company or deemed liquidation event of the Company, all of the remaining assets of the Company available for distribution to the stockholders shall be distributed among the holders of the preferred stock and common stock, pro rata based on the number of shares held by each such holder on an as converted to common stock basis.

Reserved Shares

As of December 31, 2023, the Company reserved the following shares of common stock for issuance upon conversion of the outstanding redeemable convertible preferred stock and exercise of stock options:

	December 31, 2023
Conversion of redeemable convertible preferred stock	38,413,913
Stock options available for issuance	124,136
Stock options outstanding	5,532,871
Total	44,070,920

9. Stock-Based Compensation

In 2015, the Company established the 2015 Plan, under which the Company may grant options and restricted stock to its employees and certain non-employees. The maximum number of shares of common stock reserved for issuance under the 2015 Plan is 3,405,091 shares. As of December 31 2023, there were 1,760,634 shares of common stock subject to outstanding awards under the 2015 Plan. In 2022, the Company established the 2022 Plan, under which the Company may grant options, restricted stock units, restricted stock, stock appreciation rights, dividend equivalents and other stock and cash-based awards to its employees and certain non-employees. The maximum number of shares of common stock reserved for issuance under the 2022 Plan is 3,927,889 shares. As of December 31, 2023, there were 3,772,237 shares of common stock subject to outstanding awards and 124,136 shares of common stock remaining and available for issuance under the 2022 Plan.

The Company may grant options to purchase authorized but unissued shares of the Company's common stock. Options granted under the 2015 Plan and 2022 Plan include incentive stock options that can be granted only to the Company's employees and non-statutory stock options that can be granted to the Company's employees, consultants, advisors and directors.

The exercise prices, vesting and other restrictions of the awards to be granted under the 2015 Plan and 2022 Plan are determined by the Board, except that no stock option may be issued with an exercise price less than the fair market value of the common stock at the date of the grant or have a term in excess of ten years. Options granted under the 2015 Plan and 2022 Plan are exercisable in whole or in part at any time subsequent to vesting.

Stock Options

The following table provides the assumptions used in determining the fair value of option awards for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Expected volatility	81.6%	81.8%
Risk-free interest rate	3.58% - 4.77%	1.60% - 4.35%
Expected dividend yield	0%	0%
Expected term (in years)	6.03	5.95

The weighted-average grant-date fair value of the options granted was $4.27 and $1.53 per share for the years ended December 31, 2023 and 2022, respectively. The fair value of shares vested during the years ended December 31, 2023 and 2022 was $2.41 and $1.72 per share, respectively. The fair value of shares exercised during the years ended December 31, 2023 and 2022 was $1.43 and $1.62 per share, respectively.

The following table summarizes stock option activity for the year ended December 31, 2023 (in thousands, except share and per share amounts):

	Number of Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2022	3,765,090	$ 1.62	7.66	$ 2,685
Granted	3,346,939	$ 5.78	—	
Exercised	(1,379,642)	$ 1.47	—	4,871
Forfeited/Expired	(199,516)	$ 2.37	—	
Balance at December 31, 2023	5,532,871	$ 4.12	8.55	$ 40,290
Vested and expected to vest at December 31, 2023	5,532,871	$ 4.12	8.55	$ 40,290
Exercisable at December 31, 2023	1,643,347	$ 1.76	6.47	$ 15,560

The Company has recorded stock-based compensation expense related to stock options of $1.5 million and $0.7 million for the years ended December 31, 2023 and 2022, respectively. The Company had an aggregate $13.9 million of gross unrecognized stock-based compensation expense as of December 31, 2023 remaining to be amortized over a weighted-average period of 3.36 years.

Stock-based compensation expense related to stock options recorded in the accompanying statements of operations for the years ended December 31, 2023 and 2022 was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 795	$ 542
General and administrative	733	134
Total stock-based compensation expense	$ 1,528	$ 676

The Company has not recognized and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance related to its net deferred tax assets.

10. Income Taxes

A reconciliation of the expected income tax benefit computed using the federal statutory income tax rate to the Company's effective income tax rate was as follows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Income tax computed at federal statutory rate	21.00%	21.00%
State taxes, net of federal benefit	(0.00)	(0.00)
Permanent differences	(0.84)	(0.48)
Research and development credit	2.97	1.80
Other	0.59	—
Valuation allowance	(23.72)	(22.32)
Effective income tax rate	(0.00%)	(0.00%)

The Company's deferred tax assets as of December 31, 2023 and 2022, consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	$ 18,015	$ 12,663
R&D credit	4,756	3,076
Foreign tax credit	424	424
Operating lease liabilities	97	94
Section 174	6,998	2,194
Other	266	576
Total gross deferred tax assets	30,556	19,027
Deferred tax liabilities:		
Operating lease right-of-use assets	(89)	(88)
Other	(10)	(12)
Total gross deferred tax liabilities	(99)	(100)
Net deferred tax assets	30,457	18,927
Valuation allowance	(30,457)	(18,927)
Net deferred tax asset	$ —	$ —

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available positive and negative evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. For the year ended December 31, 2023, the valuation allowance for deferred tax assets increased by $11.5 million. This increase was primarily related to the establishment of a valuation allowance against additional net operating loss, Section 174 capitalized research and experimental (R&E) costs and research credits generated in the current year.

As of December 31, 2023, the Company calculated $87.7 million and $0.2 million of federal and state net operating loss carryforwards (NOL), respectively. These amounts are subject to certain return-to-provision adjustments. Of the $87.7 million in federal NOL carryforwards, $75.5 million is not subject to expiration and the other $12.2 million begin to expire in 2030. The state NOL carryforwards begin to expire in 2040. In addition, as of December 31, 2023, the Company had $5.4 million of federal R&D credit carryovers which begin to expire in 2032 and $1.2 million of state credit carryovers, which can be carried forward indefinitely. These loss and credit carryforwards are subject to review and possible adjustment by the appropriate taxing authorities.

Utilization of the Company's NOL carryforwards and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 (Section 382) as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain shareholders or public companies in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. The Company believes one or more of these financings resulted in an ownership change as defined by Section 382, and consequently the Company's ability to fully utilize its NOL carryforwards will likely be limited. As a current analysis has not been performed, the amount of such limitations, if any, cannot be accurately estimated at this time.

As of December 31, 2023 and 2022, the Company recorded $1.0 million and $0.7 million unrecognized tax benefits on R&D credits. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its statements of income. For the years ended December 31, 2023 and 2022, no estimated interest or penalties were recognized on uncertain tax positions.

The following reconciliation of the beginning and ending amount of gross unrecognized tax benefits, excluding interest and penalties, is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Beginning balance of unrecognized tax benefits	$ 691	$ 580
Additions for prior year tax positions	53	—
Additions for current year tax positions	256	111
Ending balance of unrecognized tax benefits	$ 1,000	$ 691

None of the unrecognized tax benefits, if recognized, would impact the annual effective tax rate, due to the valuation allowance. The Company's unrecognized tax benefits are recorded as a reduction in deferred tax assets. The Company does not expect any significant increases or decreases to the Company's unrecognized tax benefits within the next 12 months. Due to the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate. The Company has not incurred any material interest or penalties as of the current reporting date with respect to income tax matters.

Tax Cuts and Jobs Act's (TCJA) amendment to Section 174 required Research and Experimental (R&E) expenditures to be capitalized in the year the amounts are incurred for amounts paid in tax years starting after December 31, 2021. The capitalized amounts are then amortized over a period of five years, if the research is performed within the U.S., or 15 years, with respect to non-U.S. based research. The amended statute specifies that amortization will begin with the midpoint of the taxable year in which expenses are paid or incurred.

11. Debt

SVB Term Loan

In January 2021, the Company entered into the Loan Agreement with SVB for a term loan in three tranches. The Company drew down Tranche A funds in January 2021 for an original principal amount of $5.0 million, in increments of $2.5 million each. The Company drew down Tranche B funds in December 2021 for an original principal amount of $10.0 million, in increments of $5.0 million each, following the achievement of certain milestones. The Tranche C funds, for which the original principal amounts are not to exceed $5.0 million, in increments of $2.5 million each, were not drawn upon in 2021 or in 2022 and are only available on the achievement of certain milestones. In addition, at any time during the term of the Loan Agreement, the Company may request that SVB make one additional term loan available to the Company in an original principal amount equal to $10.0 million. SVB, in its sole and absolute discretion, may grant or deny any such request from the Company for this term loan.

Funds received under the Loan Agreement (the Term Loan Advances) shall be interest-only during an interest-only period (the Interest-Only Period), with interest due and payable monthly on the first calendar day of each month. The Interest-Only Period, which was from January 8, 2021 through January 31, 2022, was able to be extended through July 31, 2022 if the Company achieved certain milestones (the Interest-Only Extension Milestones). The Interest-Only Period was extended to July 31, 2022 upon the drawdown of Tranche B funds in December 2021. In August and September 2022, the Company entered into amendments to the Loan Agreement (the Loan Agreement Amendments). Per the Loan Agreement Amendments, the Interest-Only Period was extended from July 31, 2022 until October 31, 2022 and the net cash proceeds related to one of the Interest-Only Extension Milestones (Interest-Only Extension Milestone 1) were increased from $50 million to $80 million. In addition, if Interest-Only Extension Milestone 1 was achieved, the Interest-Only Period would be extended until January 31, 2023. Interest-Only Extension Milestone 1 was achieved in September 2022 as a result of the sale of Series E. Thereafter, the Term Loan Advances are payable in thirty, twenty-four, or eighteen equal monthly installments (dependent on the achievement of the Interest-Only Extension Milestones) of principal plus accrued and unpaid interest (each a Term Loan Payment) beginning on the first day of the next month following the end of the Interest-Only Period and continuing on the first day of each month thereafter.

The Term Loan Advances accrue interest at a floating per annum rate equal to the greater of 3.25% above the Prime Rate or 6.50%, provided however, the interest rate shall not exceed 7.50% at any time. Immediately upon the

occurrence and during the continuance of an event of default, obligations bear interest at a rate per annum which is 5.0% above the rate that is otherwise applicable.

The Company has the option to prepay all, but not less than all, of the Term Loan Advances advanced by SVB under the Loan Agreement, provided the Company delivers written notice to SVB of its election to prepay such Term Loan Advances at least thirty days prior to such prepayment and pays, on the date of such prepayment, all outstanding principal due in connection with the Term Loan Advances, plus accrued and unpaid interest thereon, a prepayment fee (the Prepayment Fee), the Final Payment, and all other sums, if any, that have become due and payable in connection with the Term Loan Advances.

In connection with the Loan Agreement, the Company entered into a Success Fee Agreement (the Success Fee Agreement) with SVB in January 2021. In accordance with the Success Fee Agreement, the Company agreed to pay to SVB an amount equal to (a) the quotient of (i) the aggregate original principal amount of all Term Loan Advances made by SVB to the Company divided by (ii) $5 million, multiplied by (b) $125,000 (the Success Fee), upon the closing of a success fee event (the Success Fee Event) and, in the event of an initial public offering (an IPO), within five business days of closing such IPO. The Success Fee Event means the earliest to occur of any one of the following after January 8, 2021: (a) any sale, license, transfer or other disposition of all or substantially all of the assets of the Company or any of its subsidiaries; or (b) any reorganization, consolidation, or merger of the Company (or a subsidiary, but only if such subsidiary is a successor-in-interest to the Company's business) where the holders of the Company's securities (or such subsidiary's securities) before the transaction beneficially own less than 50% of the outstanding voting securities of the surviving entity after the transaction, or (c) an IPO by the Company or such subsidiary of its capital stock. The Company's obligation to pay SVB the Success Fee terminates on January 8, 2031.

On May 12, 2023, the Company repaid all outstanding principal and accrued and unpaid interest on the Term Loan Advances under the Loan Agreement and all other outstanding obligations with respect to the Term Loan Advances under the Loan Agreement and made the Final Payment. The Company's obligation to pay SVB the Success Fee remains outstanding.

12. Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss and comprehensive loss	$ (48,607)	$ (35,443)
Deemed dividend on redeemable convertible preferred stock issuances	(410)	$ (474)
Cumulative redeemable convertible preferred stock dividends	(18,781)	(7,871)
Net loss attributable to common stockholders	$ (67,798)	$ (43,788)
Denominator:		
Weighted average shares of common stock outstanding, basic and diluted	4,330,933	3,740,892
Net loss per share attributable to common stockholders, basic and diluted	$ (15.65)	$ (11.71)

The Company's potentially dilutive securities, which include redeemable convertible preferred stock and stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Basic and diluted net loss per share attributable to common stockholders is computed in conformity with the two-class method required for participating securities. The Company considers all series of its convertible preferred stock to be participating securities as the holders of such stock have the right to receive dividends on a pari passu basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stockholders is not allocated to the convertible preferred stock as the preferred stockholders do not have a contractual obligation to share in the Company's losses.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2023 and 2022 because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2023	2022
Conversion of redeemable convertible preferred stock	38,413,913	29,857,244
Stock options outstanding	5,532,871	3,765,090
Total	43,946,784	33,622,334

13. Related Parties

In 2023, the Company entered into an agreement with an outside consulting firm for the provision of interim Chief Financial Officer (CFO) services. The Company paid the consulting firm for the provision of the interim CFO services rendered less than $0.4 million and $0.1 million for services rendered for the years ended December 31, 2023 and 2022.

14. Subsequent Events

The Company has evaluated all subsequent events and transactions through March 26, 2024, the date the audited financial statements were issued, to ensure these financial statements include appropriate disclosure of events both recognized in the financial statements and events which occurred but were not recognized in the financial statements. The Company has concluded that no subsequent event has occurred that requires disclosure, except for the Reverse Stock Split and the completed initial public offering described in Note 1, and the events described below.

2024 Equity Incentive Plan

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Equity Incentive Plan (the 2024 Plan), which became effective on the date immediately preceding the date on which the Company's registration statement was declared effective by the SEC. The 2024 Plan replaced the 2022 Plan (see Note 9), as the Company's board of directors has determined to not make additional grants under the 2022 Plan following the closing of the offering. However, the 2015 and 2022 Plan will continue to govern outstanding equity awards granted under the 2015 and 2022 Plans. The 2024 Plan allows the Company to make equity-based and cash-based incentive awards to its officers, employees, directors and consultants. The number of shares initially available for issuance under awards granted pursuant to the 2024 Plan is 8,246,565 shares (which number includes 494,807 shares of common stock issuable upon the exercise of stock options, granted in connection with the offering at an exercise price equal to the initial public offering price) was the sum of (1) 10% of the number of "pricing date fully-diluted shares" (as defined in the 2024 Plan), plus (2) any shares of the Company's common stock which, as of the effective date of the 2024 Plan, remain available for issuance under the 2022 Plan, plus (3) any shares subject to outstanding awards under the 2015 Plan and 2022 Plan as of the effective date of the 2024 Plan that become available for issuance under the 2024 Plan thereafter in accordance with its terms.

2024 Employee Stock Purchase Plan

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Employee Stock Purchase Plan (the 2024 ESPP), which became effective on the date immediately preceding the date on which the Company's registration statement was declared effective by the SEC. The number of shares initially available for issuance pursuant to the 2024 ESPP was equal to a number of shares equal to 1% of the number of "pricing date fully-diluted shares" (as defined in the 2024 Plan) or 812,242 shares.

SVB Success Fee

On March 5, 2024, the Company paid $0.4 million for the Success Fee.

Exhibit 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 26, 2024, CG Oncology, Inc. ("we," "us" and "our") had one class of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock.

Description of Common Stock

General

The following description summarizes some of the terms of our common stock. Because it is only a summary, it does not contain all the information that may be important to you and is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation (the "certificate of incorporation") and amended and restated bylaws (the "bylaws"), copies of which are filed as exhibits to our most recent Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our certificate of incorporation and our bylaws for additional information.

As of March 26, 2024, our authorized capital stock consisted of 700,000,000 shares of common stock, par value $0.0001 per share, and 70,000,000 shares of preferred stock, par value $0.0001 per share.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders, including the election of directors, and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our certificate of incorporation and bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our certificate of incorporation.

Dividend Rights

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

Liquidation Rights

In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share ratably receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Rights and Preferences

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

Fully Paid and Nonassessable

The outstanding shares of common stock are duly authorized, validly issued, fully paid and nonassessable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, LLC.

The Nasdaq Global Select Market Listing

Our common stock is listed and traded on the Nasdaq Global Select Market under the symbol "CGON."

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our certificate of incorporation and our bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended 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 the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 70,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our certificate of incorporation provides that a special meeting of stockholders may be called only by our chairperson of the board, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our certificate of incorporation and bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board of Directors

Our bylaws provide that our board of directors is divided into three classes. The directors in each class serve for a three-year term, with one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our certificate of incorporation and bylaws provide that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (the Court of Chancery) (or, in the event the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts 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 our behalf; (ii) any action asserting a claim of breach of a fiduciary duty by any of our directors, officers or stockholders to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law. The provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended (the "Securities Act"), the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our certificate of incorporation also provides 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, including all causes of action asserted against any defendant to such complaint. 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. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The enforceability of similar 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 these types of provisions to be inapplicable or unenforceable. Our certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our amended and restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Charter and Bylaw Provisions

The amendment of any of the above provisions, except for the provisions which do not allow for cumulative voting, would require approval by holders of at least two thirds of the voting power of all of the then outstanding shares of stock entitled to vote thereon, voting together as a single class.

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-276729) pertaining to the CG Oncology, Inc. 2015 Equity Incentive Plan, CG Oncology, Inc. 2022 Equity Incentive Plan, CG Oncology, Inc. 2024 Equity Incentive Plan, and the CG Oncology, Inc. 2024 Employee Stock Purchase Plan of CG Oncology, Inc. of our report dated March 26, 2024, with respect to the financial statements of CG Oncology, Inc. included in this Annual Report (Form 10-K) of CG Oncology, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

Irvine, California
March 26, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Arthur Kuan, certify that:

1. I have reviewed this Annual Report on Form 10-K of CG Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:March 26, 2024

By: /s/Arthur Kuan

Arthur Kuan
Chairman and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Corleen Roche, certify that:

1. I have reviewed this Annual Report on Form 10-K of CG Oncology, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date:March 26, 2024

By /s/Corleen Roche
Corleen Roche
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of CG Oncology, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date:March 26, 2024

By /s/Arthur Kuan

Arthur Kuan
Chairman and Chief Executive Officer
(principal executive officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of CG Oncology, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date:March 26, 2024

By /s/Corleen Roche

Corleen Roche
Chief Financial Officer

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.