UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 001-41925

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 June 28, 2024 (the last trading day of the registrant's most recently completed second quarter), the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $1.4 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $31.57 per share.

As of March 21, 2025, the registrant had 76,216,855 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2024.

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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

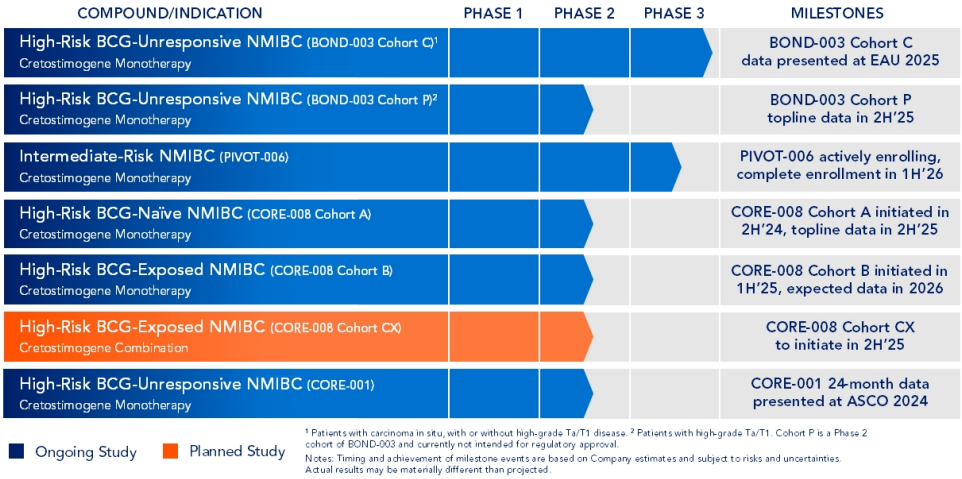
We are a late-stage clinical biopharmaceutical company focused on developing and commercializing a potential backbone bladder-sparing therapeutic for patients afflicted with bladder cancer. Our goal is to develop cretostimogene grenadenorepvec (cretostimogene), our product candidate, as an alternative to Bacillus Calmette-Guérin (BCG) in treating a broad range of bladder cancer indications. Cretostimogene is in clinical development for the treatment of patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) who are unresponsive to BCG therapy, the current standard-of-care for high-risk NMIBC. Given the limitations of currently approved therapies, the next course of treatment for these BCG-unresponsive patients is radical cystectomy, or the complete removal of the bladder, which is associated with significant social, functional and emotional burden. As such, there is a significant unmet need for effective treatments in these patients.

In anticipation of potential FDA approval, we are actively building our commercial operations, marketing, market access and patient access and field force capabilities. This includes pre-launch activities currently being executed, including scientific communication activities and engagements by our field medical organization. We are also implementing strategic initiatives to build product distribution and patient support. Our efforts are focused on ensuring that we are fully prepared to launch and deliver cretostimogene grenadenorepvec to patients and healthcare providers, if approved. We are evaluating the safety and efficacy of cretostimogene as a monotherapy in BOND-003 Cohort C, our ongoing Phase 3 clinical trial in high-risk BCG-unresponsive NMIBC with carcinoma *in situ* (CIS) and with or without Ta/T1 disease. We have completed enrollment for this cohort and reported interim data at the American Urological Association's 2024 Annual Meeting in May 2024, and topline data at the 2024 Society of Urologic Oncology (SUO) Annual Meeting in December 2024, which was updated at the 40th Annual European Association of Urology (EAU) Congress. 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) which we expect to initiate in the second half of 2025. Cretostimogene has received both Fast Track and Breakthrough Therapy designations from the FDA for the treatment of high-risk BCG-unresponsive NMIBC with CIS with or without Ta or T1 papillary tumors.

In April 2024, we initiated BOND-003 Cohort P, an exploratory study evaluating cretostimogene monotherapy in high-risk BCG-unresponsive NMIBC with only Ta/T1 disease and expect to report topline data from this Cohort in the second half of 2025. In October 2024, we initiated CORE-008 Cohort A, our Phase 2 clinical trial in high-risk NMIBC patients who are naïve to BCG treatment, including patients with CIS and with or without Ta/T1 disease and patients with only Ta/T1 disease. We intend to expand CORE-008 into the high-risk BCG-exposed population, evaluating cretostimogene as a monotherapy and in a combination therapy. We have recently completed and published the results for CORE-001, our Phase 2 clinical trial of cretostimogene in combination with pembrolizumab in patients with high-risk BCG-unresponsive NMIBC that have CIS. Additionally, we have launched our second Phase 3 clinical trial, PIVOT-006, evaluating adjuvant cretostimogene in Intermediate-Risk NMIBC following transurethral resection of the bladder tumor (TURBT). We believe cretostimogene, if approved in Intermediate-Risk NMIBC, has the potential to serve as backbone therapy, thereby alleviating the current need to prioritize treatment recipients and ration administration of BCG given its significant market shortage.

Cretostimogene, as both a monotherapy and in combination with other therapies, has shown a potential best-in-class target product profile. Topline data from the Phase 3 BOND-003 Cohort C trial that was presented as a late-breaking abstract at the 2024 SUO Annual Meeting showed that cretostimogene, as a monotherapy in patients with high-risk BCG-unresponsive NMIBC, achieved a 74.5% complete response (CR) rate at any time, as of the data cutoff date on September 30, 2024. Additionally, as of the data cutoff of September 30, 2024, Kaplan-Meier estimates for CR rate at 12 and 24 months were 50% (95% confidence interval (CI), 39.6-58.9%) and 41% (95% CI, 30.4-50.8%), respectively. Progression-free survival (PFS) at 12 months was 97.3% with no patients progressing to muscle invasive cancer, and cystectomy-free survival at 12 months was 90.0%. The estimated duration of response (DoR) probability at 12 months and 24 months was 63.5% (95% CI, 51.2-73.4%) and 56.6% (95% CI, 43.3-67.8%), respectively. Median DoR was not reached but, as of the cutoff date, was greater than 27 months. There were no Grade 3 or higher treatment-related adverse events (TRAEs) or deaths reported. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, dysuria, micturition urgency, and hematuria. No treatment-related discontinuation of cretostimogene was observed, and 97.3% of patients completed all protocol-defined treatments, demonstrating favorable patient adherence and compliance. The study was updated in a late-breaking abstract at the 40th Annual EAU Congress, showing CR rate at any time improved to 75.5%, with median DoR not reached but exceeds 28 months as of the data cutoff of January 20, 2025. In addition, final results from the open-label Phase 2 CORE-001 clinical trial of intravesical cretostimogene in combination with pembrolizumab in high-risk BCG-unresponsive NMIBC were presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting and published in Nature Medicine. As of the May 17, 2024 data cutoff, 29 of the 35 (82.9%; 95% CI, 70.4-95.3%) patients achieved a CR at any time, with 57.1% (n=20/35, 95% CI, 39.5-73.2%)) of patients maintaining a CR at 12 months, and 54.3% (n=19/35, 95% CI, 36.9-70.8%) of patients maintaining a CR at 24 months, indicating that 95.1% of patients in CR at 12 months remain in CR at 24 months. The safety profile was favorable, with no overlapping or synergistic toxicity observed. Adverse events attributed to cretostimogene were Grade 1 or Grade 2 and self-limited. We have presented the 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. Based on these encouraging data, we are working toward the submission of a BLA for cretostimogene as a treatment for patients with high-risk BCG-unresponsive NMIBC, which we expect to initiate in the second half of 2025. We intend to evaluate cretostimogene for use in a broad range of bladder cancer indications, as shown in our pipeline below.

Our Cretostimogene Pipeline



Our Strengths

We believe our product candidate, cretostimogene, has a potential best-in-class target product profile that supports our vision of cretostimogene as a potential backbone bladder-sparing therapy in bladder cancer. The key differentiating factors include:

- **Favorable monotherapy data.** Cretostimogene demonstrated sustained, durable complete responses in high-risk BCG-unresponsive NMIBC, with a 75.5% CR at any time, and 63.7% of evaluable responders maintaining their response for at least 12 months and 58.7% at 24 months. This shows that a significant number of patients who achieved a complete response at one year maintained it at two years, as of January 20, 2025 in our ongoing Phase 3 BOND-003 trial.

- **Strong safety and tolerability profile.** No Grade 3 or higher TRAEs were observed and no patient discontinued cretostimogene due to TRAEs as of January 20, 2025 in our ongoing Phase 3 BOND-003 trial. The median time to TRAE resolution was one day.

- **Simple route of administration.** Similar to the standard-of-care BCG therapy, cretostimogene is administered intravesically, which urology practices perform regularly. This is unlike some treatment procedures that require a urologist to perform a cystoscopic examination that involves local anesthesia.

- **Potential for combination with other therapies.** Cretostimogene, in combination with the checkpoint inhibitor (CPI) pembrolizumab produced an 82.8% CR at any time in our completed Phase 2 CORE-001 clinical trial, with no Grade 3 or higher TRAEs attributable to cretostimogene, demonstrating the potential benefits of using cretostimogene in a combination therapy.

- **Potential broad applicability across bladder cancer indications.** Due to its novel dual mechanisms of action, cretostimogene has the potential to address a broad range of bladder cancer indications, including high-risk BCG-naïve, exposed and unresponsive NMIBC, as well as intermediate-risk NMIBC and 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 2025, more than 85,000 people will be diagnosed with bladder cancer and that the disease will result in nearly 17,500 deaths. An estimated 730,044 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 making 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 whose disease becomes unresponsive to BCG treatment. While radical cystectomy is the current guideline recommended treatment for BCG-unresponsive NMIBC, only approximately 6% of patients with NMIBC 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 patients with NMIBC is the ongoing shortage of BCG which has restricted patient eligibility to high-risk BCG-naïve NMIBC 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 initiated CORE-008, an open-label, multi-arm, multi-cohort Phase 2 clinical trial designed to assess the safety and efficacy of cretostimogene when administered as monotherapy in high-risk BCG-exposed and BCG-naïve NMIBC patients. BCG-exposed patients are classified as those 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 NMIBC is classified in patients who have not received any prior BCG therapy.

In addition to NMIBC, we have evaluated 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, a single-arm, exploratory investigator-sponsored clinical trial, intravesical cretostimogene was evaluated in combination with the CPI nivolumab in patients with MIBC ineligible for cisplatin chemotherapy prior to radical cystectomy. Results were published in Nature Medicine online in November 2024.

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:

- **Pursue FDA approval of cretostimogene as monotherapy in high-risk BCG-unresponsive NMIBC.** 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 topline data in December 2024. Given the significant unmet need in this indication, the FDA published initial guidance in 2018 (revised in August 2024) 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 Phase 3 PIVOT-006 clinical trial; and (2) patients with high-risk BCG-exposed and BCG-naïve NMIBC in our open-label multi-cohort Phase 2 CORE-008 clinical trial. Our goal is to alleviate the current need to prioritize treatment recipients and ration administration of BCG given its significant market shortage. With approximately 85,000 new U.S. diagnoses per year and over 730,044 patients living with bladder cancer in the United States, according to the American Cancer Society, we believe cretostimogene, if approved, has the potential to address the significant unmet need in bladder cancer treatment.

- **Continue to evaluate cretostimogene in combination with other therapies, such as checkpoint inhibitors, to potentially further enhance its clinical utility across various stages of bladder cancer.** As of January 20, 2025, cretostimogene had been administered in over 360 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 are evaluating the safety and efficacy of cretostimogene in combination with other therapies in addition to our monotherapy trials. These include our new Phase 2 CORE-008 multi-cohort trial in high-risk NMIBC. We believe our approach to combine cretostimogene with other therapeutics across several bladder cancer indications may enhance the potential utility of our product candidate beyond our core strategy of targeting intermediate- and high-risk NMIBC via cretostimogene monotherapy.

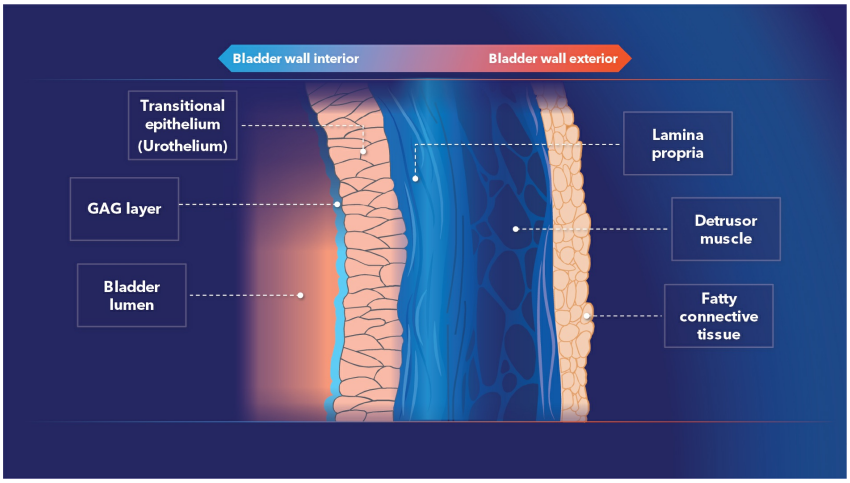
•**Build our operational capabilities to successfully commercialize cretostimogene**. In preparation for potential FDA regulatory approval for cretostimogene, we are in the early stages of building in-house sales, marketing and market access capabilities to successfully commercialize cretostimogene in 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 the largest 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. 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 chemistry, manufacturing and controls expertise and relationships to scale commercialization efforts**. 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 in-house chemistry, manufacturing and controls (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. Our world class CMC Advisory Board provides 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

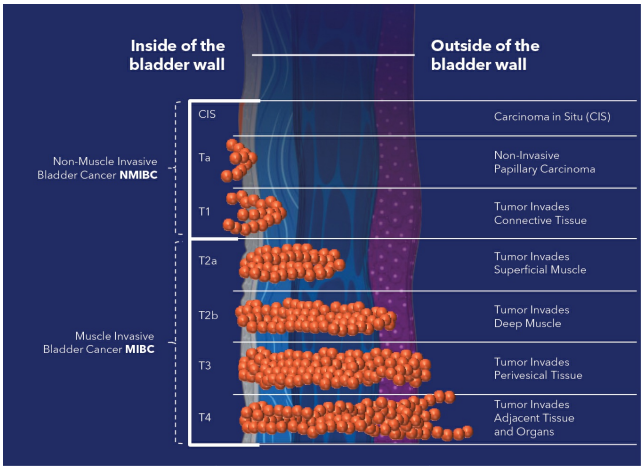


The American Cancer Society estimates that in 2025, approximately 85,000 people will be diagnosed with bladder cancer in the United States and that it will result in nearly 17,500 deaths. Notable is the disease prevalence with an estimated 730,044 people in the United States living with the disease. 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 patients with high-risk 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. Patients with bladder cancer 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 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 variant histology such as 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 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, 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 whose disease becomes unresponsive to BCG treatment.

Patient Classification

NMIBC is a heterogeneous disease with significant variation in individual risk of recurrence and progression to MIBC. Within NMIBC, tumors are stratified as low, intermediate or high-risk based on several factors including tumor stage, grade, tumor size, multifocality, recurrence and presence of other high-risk pathological features. Numerous iterations of disease classification guidelines have evolved over time, primarily from medical professional societies such as the AUA.

A key recommendation from the AUA is that patients with high-risk disease should receive intravesical BCG treatment. Thus, within the high-risk stratification, NMIBC falls on a spectrum extending from BCG-naïve NMIBC (never treated or treated >24 months ago, as defined by the International Bladder Cancer Group (IBCG) Consensus Statement) to BCG-unresponsive NMIBC.

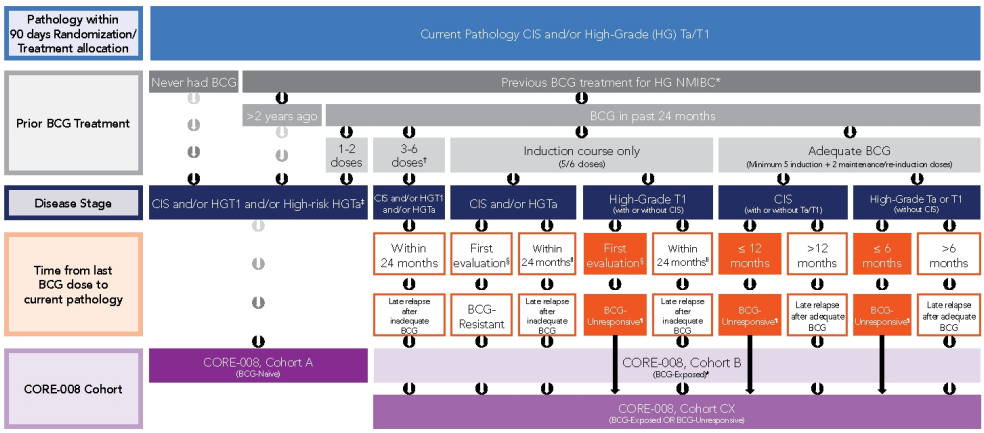
In February 2018, the FDA published draft guidance titled "BCG-Unresponsive Non muscle Invasive Bladder Cancer: Developing Drugs and Biologics for Treatment," in order to assist sponsors in the development of drugs, including biologics, for the treatment of BCG-unresponsive NMIBC. This guidance, which was revised in August 2024, provides disease-state definitions and advice on patient selection, risk stratification, and clinical trial design in BCG-unresponsive NMIBC.

According to the 2018 and the 2024 draft revised 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. Specifically, NMIBC will be classified as BCG-exposed in many cases including: (1) persistent or recurrent high-grade Ta or CIS-containing disease at the first evaluation following 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.

The chart below shows the various treatment pathways leading to classification as BCG-naïve, BCG-exposed, or BCG-unresponsive NMIBC.



Limited Treatment Options for Patients with High-Risk BCG-unresponsive NMIBC

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 NMIBC, is 18% at six months. CIS-containing tumors are typically not considered resectable, further limiting treatment options for patients with BCG-unresponsive NMIBC. 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 DoR being 16.2 months. The percentage of trial participants with a CR declined to 19% at 12 months. Among the trial cohort involving high-risk BCG-unresponsive 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, a non-replicating adenoviral-based gene therapy produced by Ferring that activates interferon α2b, was approved by the FDA in December 2022 to treat high-risk BCG-unresponsive NMIBC with CIS, 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).

In April 2024, nogapendekin alfa inbakicept (nogapendekin), an IL-15 agonist produced by ImmunityBio, in combination with BCG, was approved by the FDA to treat high-risk BCG-unresponsive NMIBC with CIS, with or without papillary tumors. The approval was based on a Phase 2/3 clinical trial showing 62% of BCG-unresponsive NMIBC achieved a CR and 36% of patients maintained a CR at 12 months following treatment with nogapendekin. While Grade 3 or 4 treatment-related adverse events were not reported, serious TRAEs occurred in 16% of patients and 7% of patients had treatment-related discontinuation.

Based in part on a retrospective analysis of patients with high-risk NMIBC, 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 different stages NMIBC are in various stages of clinical development and regulatory approval. There are multiple companies that have reported drug candidates in clinical development, including Urogen Pharma, Inc.'s UGN-102, an IVE-delivered DNA synthesis inhibitor, mitomycin, in reverse thermal gel formulation for treatment of low-grade intermediate-risk NMIBC, Janssen Pharmaceuticals, Inc.'s TAR-200, 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 over a one-week period, enGene, Inc.'s EG-70, an IVE-delivered IL-2 and RIG-I dual-agonist, and Protara Therapeutics, Inc.'s TARA-002, an IVE-delivered cell therapy that elicits a TH1 pro-inflammatory cytokine response.

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, but commonly requires an ostomy appliance for urinary diversion. Despite being the current guideline recommended option, only approximately 6% of patients with high-risk BCG-unresponsive NMIBC 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 complication, 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 patients with bladder cancer.

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 patients with bladder cancer.

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 only, with maintenance therapy limited to 12 months. The NCCN and AUC/SUO guidelines no longer recommend BCG therapy for intermediate-risk NMIBC, instead indicating that BCG should be prioritized for high-risk NMIBC 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 primary and backbone therapy across several bladder cancer indications, if successfully developed and approved.

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

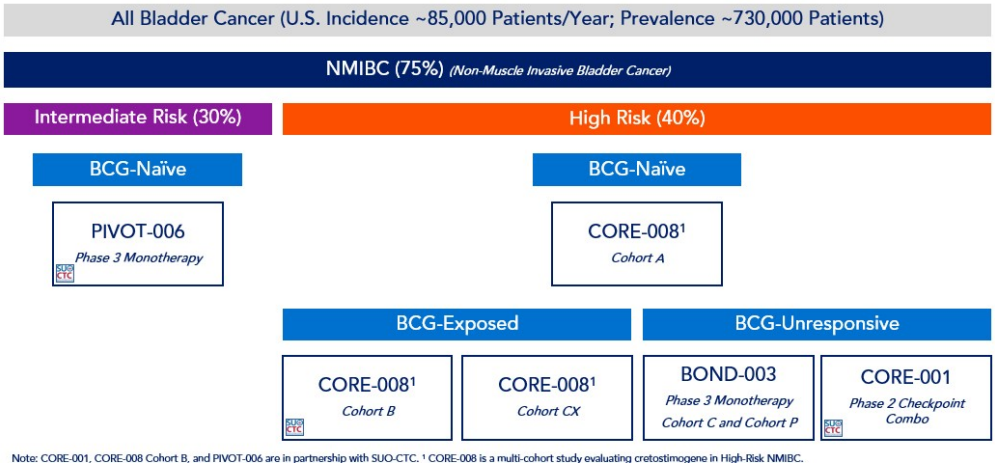
Cretostimogene is an investigational oncolytic immunotherapy with a dual mechanism of action designed both to eliminate cancer cells directly by selective replication and indirectly activating an anti-tumor immune response. Our ongoing open-label Phase 3 clinical trial, BOND-003, is designed to assess the safety and efficacy of cretostimogene in high-risk BCG-unresponsive NMIBC when administered as a monotherapy. We have completed enrolling patients with high-risk NMIBC with CIS and with or without Ta/T1 disease who are unresponsive to BCG in the BOND-003 Cohort C trial and reported topline data in December 2024, which was updated in March 2025. We believe that this trial could serve as the basis for a BLA submission to the FDA, which we expect to initiate in the second half of 2025. We have also completed CORE-001, our open-label Phase 2 clinical trial evaluating the safety and efficacy of cretostimogene when used in combination with pembrolizumab in this same patient population. We believe the clinical trial results observed to date reflect the differentiated therapeutic potential of cretostimogene.

Cretostimogene, as both a monotherapy and in combination with other therapies, has shown a potential best-in-class target product profile. Topline data from the Phase 3 BOND-003 Cohort C trial that was presented as a late-breaking abstract at the 2024 SUO Annual Meeting showed that cretostimogene, as a single agent, achieved a 74.5% CR at any time in high-risk BCG-unresponsive NMIBC. As of the data cutoff of September 30, 2024, by Kaplan-Meier estimate, 63.5% and 56.6% of patients remained in response at 12 months or greater and at 24 months or greater, respectively, while the median DoR was not reached and exceeds 27 months. There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria. No treatment-related discontinuation of cretostimogene was observed, and 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. The study was updated in a late-breaking abstract at the 40th Annual EAU Congress, showing CR rate at any time improved to 75.5%, with median DoR not reached but exceeds 28 months as of the data cutoff of January 20, 2025.

We are also evaluating the tolerability and efficacy of cretostimogene monotherapy in high-risk BCG-unresponsive NMIBC with only Ta/T1 disease in BOND-003 Cohort P, and have initiated CORE-008 Cohort A, our Phase 2 clinical trial in high-risk NMIBC which are naïve to BCG treatment, including patients with CIS and with or without Ta/T1 disease and patients with only Ta/T1 disease. We recently expanded CORE-008 into the BCG-exposed population (Cohort B), evaluating cretostimogene as a monotherapy and intend to add a third cohort (Cohort CX) in a combination approach. In intermediate-risk NMIBC, 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 NMIBC following TURBT.

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



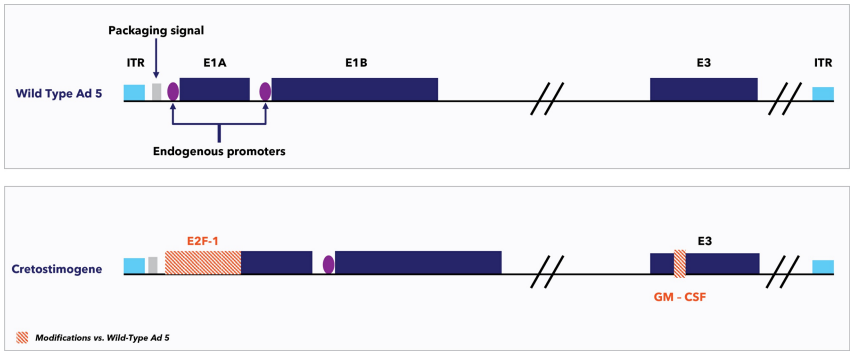
We believe patients with NMIBC with BCG-unresponsive disease are unlikely to benefit from further BCG therapy. Additionally, given the patient burden and mortality associated with cystectomy, bladder preservation through the avoidance or delay of cystectomy is an intended outcome of new therapeutic product candidates for bladder cancer. We believe our approach is supported by the February 2018 draft FDA guidance, revised in August 2024, regarding clinical trial design targeting BCG-unresponsive, CIS-containing NMIBC that stated that a single-arm trial with CR rate as the primary endpoint, taking DoR into account, may be appropriate for full approval. As of December 31, 2024, there were three products that have received full FDA approval based on data from single-arm clinical trials following the issuance of the guidance.

Cretostimogene Grenadenorepvec

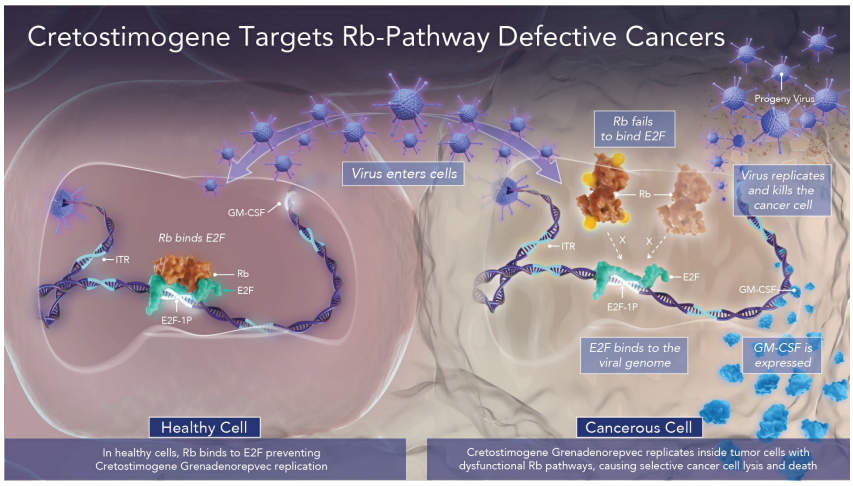
Cretostimogene is an investigational oncolytic immunotherapy that has been designed to selectively replicate in retinoblastoma (Rb)-E2F gene pathway-altered cells present in the majority of UCs and trigger an anti-tumor immune response. Cretostimogene enters the tumor by binding to Coxsackievirus and 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-E2F altered 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-E2F altered 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



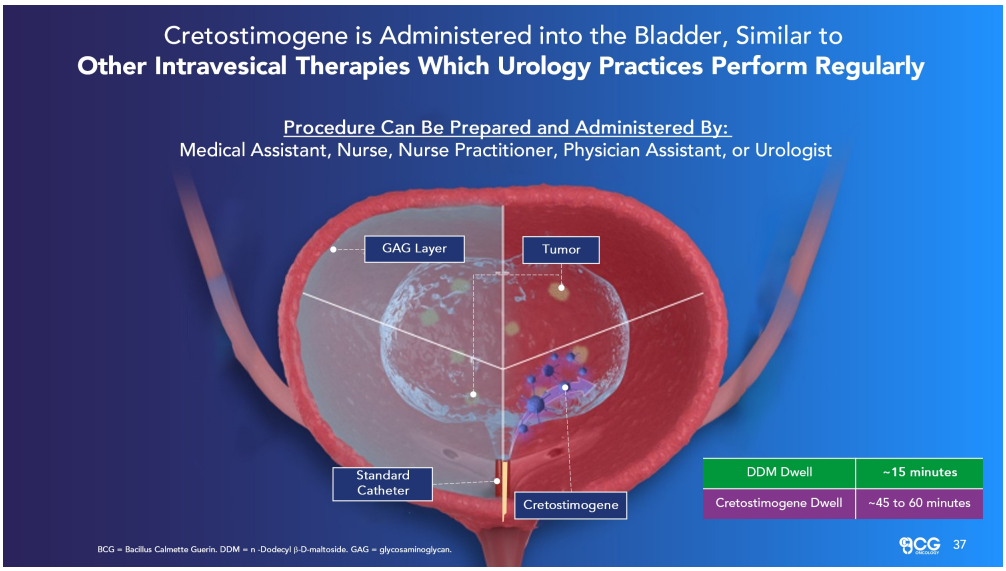
Overview of Cretostimogene's Replication Selectivity in Healthy Versus Cancerous Cells with Defective Rb-Pathway



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 an excipient 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. We have now streamlined this process and eliminated the saline and DDM wash steps. 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 $1x10^{12}$ viral particles (VPs) per milliliter to patients who had refused radical cystectomy and with high-risk CIS-containing NMIBC, with or without Ta/T1 tumors, and a cohort of Ta/T1 only tumors, that had failed BCG therapy. The trial included a heterogenous mixture of BCG-exposed and BCG-unresponsive NMIBC.

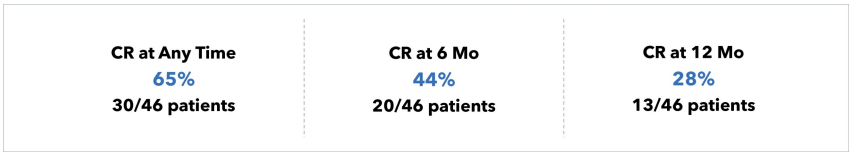
A total of 65 patients were enrolled, which included 46 CIS patients, with or without Ta/T1 disease, and 19 patients with Ta/T1 disease. Patients received an initial induction course of six weekly administrations. Patients who achieved a CR at month six received six weekly maintenance doses of cretostimogene using the same concentration. Patients whose disease did not respond to the first induction course received accelerated maintenance at month three to four, which involved early administration of the maintenance normally provided at six months. 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 40 (61.5%) patients achieving a CR at any timepoint, the median DoR had yet to be reached after 18 months, with 21 patients (52.5%) without disease progression at 18 months. In most patients, responses occurred early in the treatment course. Specifically in the 46 patients with high-risk CIS-containing NMIBC, 30 (65.2%; 95% CI, 49.7-78.2%) 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 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 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, and the revised draft guidance in August 2024, 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.

The initial induction course of therapy is six weekly doses of cretostimogene containing $1x10^{12}$ 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 and reported topline data in December 2024, which was updated in March 2025.

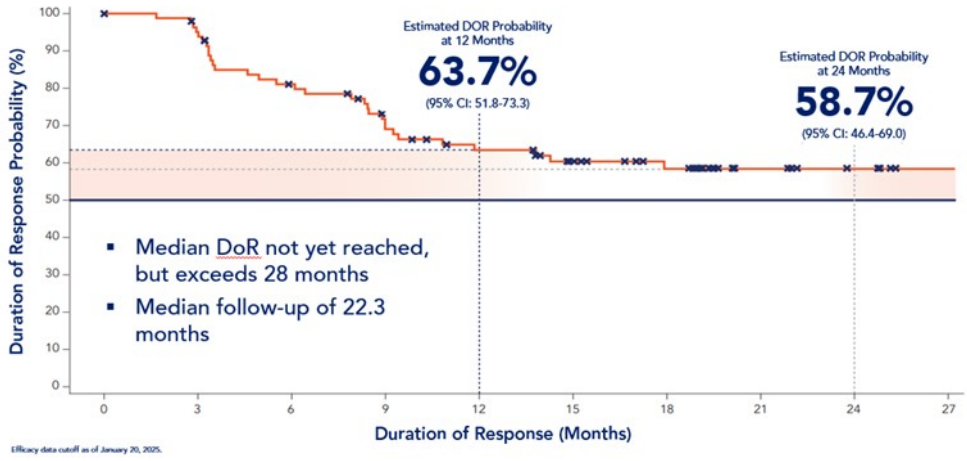
Enrollment of Additional Cohort in BOND-003 Trial

We added a 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, Ta or T1 without CIS that have received adequate BCG therapy. The primary endpoint of this cohort is overall event-free survival, with secondary endpoints including safety, high-grade recurrence-free survival (RFS), low-grade RFS, PFS, cystectomy-free survival, and bladder cancer specific survival. We expect to report topline data in the second half of 2025.

Overview of Topline Data from BOND-003 Cohort C Trial

Topline data from the Phase 3 BOND-003 Cohort C that was presented as a late-breaking abstract at the 2024 SUO Annual Meeting showed that cretostimogene, as a single agent, achieved a 74.5% complete response (CR) at any time in high-risk BCG-unresponsive NMIBC. As of the data cutoff of September 30, 2024, by Kaplan-Meier estimate, 63.5% and 56.6% of patients remained in response at 12 months or greater and at 24 months or greater, respectively, while the median DoR was not reached but exceeds 27 months. The study was updated in a late-breaking abstract at the 40th Annual EAU Congress, showing CR rate at any time improved to 75.5%, with 63.7% and 58.7% of patients remaining in response at 12 months or greater and at 24 months or greater, respectively, while median DoR was not reached but exceeds 28 months as of the data cutoff of January 20, 2025. The chart below shows a sustained DoR observed in patients enrolled in the BOND-003 Cohort C trial as of the January 20, 2025 data cutoff.

Overview of Duration of Response Results from BOND-003 Cohort C Trial



Overview of Interim Safety Data from BOND-003 Trial

Cretostimogene was generally well-tolerated in this trial as of the January 20, 2025 safety data cutoff, with mostly Grade 1 or Grade 2 adverse events reported and no Grade 3 or higher TRAEs or deaths reported. The median time to TRAE resolution was one day. There were no treatment discontinuations due to TRAEs, and 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. Two patients (1.8%) had SAEs, including Grade 2 noninfective cystitis, and Grade 2 clot retention, both of which resolved.

Overview of Translational Data from BOND-003 Trial

Translational data shared at the EAU Congress showed the level of cretostimogene peaked immediately after instillation, which was sustained locally for 4-5 days. Furthermore, intravesical delivery of cretostimogene reduces anti-drug antibody neutralization, thereby preserving therapeutic efficacy. There was no systemic exposure, with cretostimogene levels remaining below the limit of detection, providing evidence that post cretostimogene treatment close contact precautions are not needed. This information supports the current dosing schedule.

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

Overview of CORE-001 Trial Design

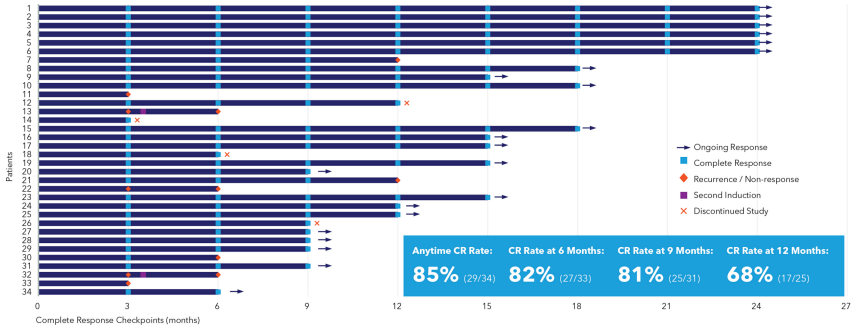
CORE-001 was a Phase 2 single-arm, open-label clinical trial of cretostimogene administered in up to 35 patients with high-risk BCG-unresponsive NMIBC that have CIS-containing tumors, in combination with pembrolizumab, following disease resection. Patients that demonstrate a CR after an initial six-week induction phase of weekly cretostimogene administrations, dosed at a concentration of $1x10^{12}$ 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 endpoint of the CORE-001 trial is CR at 12 months, with secondary endpoints including CR at any time, DoR and PFS. We 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 intravesical cretostimogene in CORE-001 is similar to BOND-003, while pembrolizumab is administered pursuant to its approved dosing schedule.

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

Final results from the CORE-001 demonstrated that, as of the May 17, 2024 data cutoff, 29 of the 35 (82.9%; 95% CI, 70.4-95.3%) 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 81.8% (n=27/33) of the evaluable patients maintaining a CR at six months and 68.0% (n=17/25) of evaluable patients maintaining a CR at 12 months, each as of the cutoff date. Presented in the chart below is a summary of the interim results observed in patients enrolled in the CORE-001 trial.

Overview of Final Results from CORE-001 Trial



Final data have been published in Nature Medicine online in June 2024.

Overview of Safety Data from the CORE-001 Trial

As of the May 17, 2024 data cutoff, 29 of the 35 (82.9%; 95% CI, 70.4-95.3%) patients achieved a CR at any time, with 57.1% (n=20/35, 95% CI, 39.5-73.2%) of patients maintaining a CR at 12 months, and 54.3% (n=19/35, 95% CI, 36.9-70.8%) of patients maintaining a CR at 24 months, indicating that 95.1% of patients in CR at 12 months remain in CR at 24 months. The safety profile was favorable, with no overlapping or synergistic toxicity observed. Adverse events attributed to cretostimogene were Grade 1 or Grade 2 and self-limited.

Additional, Ongoing Clinical 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 (IR-NMIBC) following TURBT. This is a two-arm trial enrolling up to 364 patients with IR-NMIBC, one arm to be administered cretostimogene following the standard of care TURBT with the second arm receiving the standard of care TURBT only. If IR-NMIBC recurrence is noted in the surveillance arm, patients will be eligible to receive intravesical cretostimogene. 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.

Cretostimogene Monotherapy for High-Risk NMIBC

Phase 2 CORE-008 Clinical Trial

The 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. Each cohort is expected to enroll at least 60 patients. BCG-exposed patients are classified as those with NMIBC 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 patients with NMIBC who have not received any prior BCG therapy. After an induction course of therapy of six weekly doses of cretostimogene containing $1x10^{12}$ 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 initiated Cohort A in BCG-naïve patients in the second half of 2024, with topline data expected in the second half of 2025. We also initiated Cohort B in BCG-exposed patients in the first half of 2025. Topline data from Cohort B is expected to be available in 2026.

Completed 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 patients with high-risk NMIBC that progresses 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 evaluated the use of intravesical 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 21 cisplatin-ineligible patients with no evidence of distant metastases prior to radical cystectomy. Intravesical 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.

Among the 21 evaluable patients, the combination of cretostimogene and nivolumab had produced a pathologic complete response (pCR) in 42.1% (n=19/21; 95% CI, 20-64%). Cretostimogene was well-tolerated among trial participants. There were no dose limiting toxicities or Grade 3 or higher treatment related or immune related adverse events. Additionally, 95% of participants completed all study treatments. There was no delay in time to radical cystectomy and no unexpected surgical complications from treatment. Importantly, investigators found that treatment response was not correlated with pre-treatment PD-L1 levels, and that the majority of PD-L1 negative patients had CRs. Additionally, the formation and maturation of tertiary lymphoid structure (TLS) in responders were observed, suggesting the mechanistic onset of anti-tumor humoral memory. TLS are special structures that form in areas of chronic inflammation and assist the immune system to fight cancer. These final clinical and translational results were published in Nature Medicine online in November 2024.

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 patients with high-risk BCG-unresponsive NMIBC, 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

As we prepare for potential FDA approval of cretostimogene for high-risk NMIBC patients unresponsive to BCG, we believe we have established a seasoned executive leadership team and commercial leadership organization with a proven track record for successfully bringing urology and bladder cancer products to market. Additionally, we continue to build our commercial capabilities and commercial infrastructure to ensure market development and commercial launch readiness.

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 milestones, and 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 March 27, 2025, we own seven patent families comprising four issued U.S. patents, nine issued foreign patents in Australia, China, Europe (Unitary Patent), Japan, Singapore, Spain, and the United Kingdom, two pending U.S. non-provisional patent applications, three pending U.S. provisional patent applications, and twelve pending patent applications in jurisdictions outside of the United States.

With regard to cretostimogene, we own four issued U.S. patents and nine issued patents in Australia, China, Europe (Unitary Patent), Japan, Singapore, Spain and the United Kingdom 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 two pending U.S. applications and eleven 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 three pending U.S. provisional patent applications, and any patents that issue from these applications are expected to expire between 2036 and 2045, 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 (EC) 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 EC 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 Patient Protection and Affordable Care Act (ACA), 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.

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 ACA, was enacted in the United States and substantially changed the way healthcare is financed by both the government and private insurers.

In addition, other legislative changes and amendments have been proposed and adopted since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, for single source and innovator multiple source drugs, effective 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, the Inflation Reduction Act of 2022 (IRA) was signed into law. Among other things, the IRA requires manufacturers of certain high-expenditure, single-source biologics that have been on the market for at least 11 years to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap (the "Medicare Drug Price Negotiation Program"); 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 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services (CMS) and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may, for example, include directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation (CMMI) to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo (Loper Bright), the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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, 2024, we had 113 employees, all of whom were full-time and 42 of whom were engaged in research and development activities. Twenty-eight of our employees held advanced medical degrees. 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.

Corporate Information

We incorporated in Delaware in November 2017. Our corporate headquarters are located at 400 Spectrum Center Drive, Suite 2040, Irvine, California 92618, and our telephone number is (949) 409-3700. 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. Further, our references to website URLs are intended to be inactive textual references only.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, together with the other information contained in this Annual Report, including our consolidated 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.

Risk Factors Summary

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

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 rely on third parties for the manufacture and shipping of cretostimogene for clinical development and if approved by the FDA, will rely on third parties for the manufacture, supply and shipping of cretostimogene for commercialization, 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.

•Because cretostimogene is an investigational product candidate and has not received FDA approval, our third party contract manufacturers have not produced cretostimogene at commercial levels and have not yet successfully passed the necessary regulatory inspections to produce cretostimogene for commercial use.

Risks Related to Commercialization of Cretostimogene and any Future Product Candidates

•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.

•We are in the early stages of building our internal marketing and sales organization and have no experience as a company in commercializing products, and we will 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 any product revenue.

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.

•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.

Risks Related to Our Intellectual Property

•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.

Risk Factors

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, including the full data readouts from the ongoing Phase 3 clinical trials for cretostimogene;

•acceptance of regulatory submissions by the U.S. 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, 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 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.

We 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 have previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. 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.

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. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects. 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. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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 IRBs or 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 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.

Cretostimogene, as both a monotherapy and in combination with other therapies, has shown a potential best-in-class target product profile. Topline data from the Phase 3 BOND-003 Cohort C trial that was presented as a late-breaking abstract at the 2024 SUO Annual Meeting showed that cretostimogene, as a single agent, achieved a 74.5% complete response (CR) at any time in high-risk BCG-unresponsive NMIBC, which was updated at the 2025 Annual EAU Congress to 75.5%. As of the data cutoff of September 30, 2024, by Kaplan-Meier estimate, 63.5% and 56.6% of patients remained in response at 12 months or greater and at 24 months or greater, respectively, while the median DoR was not reached but exceeds 27 months. There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria. No treatment-related discontinuation of cretostimogene was observed, and 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. While we believe these data from our Phase 3 BOND-003 trial will support our BLA submission for cretostimogene, the FDA may determine that our Phase 3 BOND-003 data is insufficient to accept for filing such BLA or for BLA approval and may impose requirements for BLA resubmission, and even if filed by the FDA they may impose requirements to conduct additional clinical trials, or other significant and time-consuming requirements related to clinical data, nonclinical studies or manufacturing, or may issue a complete response letter (CRL). 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, which would 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 severity 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 and have reported topline data from the Phase 3 BOND-003 Cohort C trial for cretostimogene, we have not as an organization completed the pivotal clinical trials for cretostimogene 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 two Phase 2 clinical trials 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, while we have had interactions with the FDA regarding our planned BLA submission for cretostimogene, we cannot be certain that our Phase 3 BOND-003 Cohort C trial for cretostimogene will be sufficient to support a BLA submission, even if we believe the results are sufficiently positive, or whether 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. For example, topline data from the Phase 3 BOND-003 Cohort C trial that was presented as a late-breaking abstract at the 2024 SUO Annual Meeting showed that cretostimogene, as a single agent, achieved a 74.5% CR at any time in high-risk BCG-unresponsive NMIBC, which was updated to 75.5% at the 2025 Annual EAU Congress. 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, including with respect to the topline data from the Phase 3 BOND-003 Cohort C trial. 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, including with respect to the topline data we reported from the Phase 3 BOND-003 Cohort C trial, 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 with carcinoma in-situ with or without Ta or T1 tumors to improve 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 with carcinoma in-situ with or without Ta or T1 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 with carcinoma in-situ with or without Ta or T1 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, 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 and sufficient 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 be 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, there are personnel shortages at the FDA or other regulatory agencies, 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 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, while we are in the process of establishing long-term commitment or supply agreements for the commercial supply of cretostimogene, we do not currently have any such 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 devote appropriate resources to manufacture our product, or 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.

Despite our efforts, we may encounter unforeseen challenges and risks that could impact the effectiveness of our supply chain enhancements. These challenges may include, but are not limited to, regulatory hurdles, supply chain disruptions, and potential delays in the manufacturing and distribution processes. As a result, our ability to ensure a reliable and efficient supply chain for cretostimogene may be compromised, which could adversely affect our business operations and financial performance.

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 ACA, signed into law on March 23, 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. 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. For example, on October 15, 2024, UroGen announced that the FDA accepted UroGen's NDA for UGN-102 (intravesical mitomycin/sterile hydrogel) in LG-IR-NMIBC, and set a PDUFA action date of June 13, 2025. In addition, Johnson & Johnson announced on January 15, 2025 that it initiated the submission of an NDA with the FDA for TAR-200 for the treatment of patients with BCG-unresponsive high-risk non-muscle-invasive bladder cancer (HR-NMIBC) with CIS, with or without papillary tumors. If UGN-102 or TAR-200 receives FDA approval and enter the bladder cancer market prior to the approval of cretostimogene, the market for cretostimogene may be adversely affected and our opportunity to generate revenue from the sale of cretostimogene, if approved, could be adversely affected.

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 are in the early stages of building our marketing and sales organization and have no experience as a company in commercializing products, and we will 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 are currently in the early stages of building our internal sales and marketing capabilities to prepare for the commercialization of cretostimogene, if approved, and we have never 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 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 $88.0 million and $48.6 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $218.0 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 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 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 many 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, development and, if approved, commercialization 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, potentially seek regulatory approval for cretostimogene and any future product candidates we may develop, and build out internal sales and marketing capabilities to prepare for the commercialization of cretostimogene, if approved. 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.

We believe, based on our current operating plan, that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. 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.

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 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, which could disrupt our operations.

As of December 31, 2024, we had 113 full-time employees. As we continue development and pursue the potential commercialization of cretostimogene or any future product candidates, 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.

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 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 ACA, as amended by the Health Care and Education Reconciliation Act of 2010 was enacted in the United States, which substantially changed healthcare financing, access and delivery by both governmental and private insurers.

Since its enactment, there have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA.

For example, on August 16, 2022, the IRA was signed into law. Among other things, the IRA (i) directs HHS to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Drug Price Negotiation Program") 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 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 15, 2024, HHS announced the agreed-upon price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may, for example, include directives to reduce agency workforce, rescinding a Biden administration executive order tasking the CMMI to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

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 are subject to a variety of stringent and evolving U.S. and foreign data protection, privacy and security obligations, including laws, regulations, standards and contractual provisions, which could increase compliance costs, and any actual or perceived failure by us or our service providers 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. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) confidential business and patient health information, personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, business plans, transactions, financial information, 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 are and 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 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, often 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.

If our information technology systems or those third parties with whom we work or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to material disruption of our development programs, compromise of sensitive information related to our business, inability to access 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 could be unable to anticipate these techniques or implement adequate preventative measures. Remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Security incidents often remain undetected for an extended period and could affect our operations. 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 have 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. (ANI) 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. The court has most recently set a trial date of July 21, 2025. While we continue to 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.

Despite our efforts, we may encounter unforeseen challenges and risks that could impact the effectiveness of our supply chain enhancements. These challenges may include, but are not limited to, regulatory hurdles, supply chain disruptions, and potential delays in the manufacturing and distribution processes. As a result, our ability to ensure a reliable and efficient supply chain for cretostimogene may be compromised, which could adversely affect our business operations and financial performance.

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, 2024, 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. Under current law, NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in a taxable year is limited to 80% of taxable income in such year.

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. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027. 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 be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq.

Prior to our initial public offering in January 2024, there was no public market for our common stock and our common stock only began trading on the Nasdaq Global Select Market (Nasdaq) in January 2024. We can provide no assurance that we will be able to sustain an active trading market for our common stock. 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;

•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 27, 2025, our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 16.7% 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.

Holders of a significant number of shares of our outstanding common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting. 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 the reduced disclosure requirements applicable to emerging growth 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.

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, including threatened or actual trade wars and tariffs. 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. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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.

When we lose our status as an "emerging growth company," 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 our management are required to meet 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 implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, and confidential information that is proprietary, strategic or competitive in nature.

We have developed our cybersecurity risk management program ("cybersecurity framework"), including a cybersecurity incident response plan, modeled after the National Institute of Standards and Technology Cybersecurity Framework's (NIST CSF) principles: Identify, Protect, Detect, Respond, Recover, and Govern, and our cybersecurity framework is intended to address current vulnerabilities and anticipate future cybersecurity threats and risks to our Information Systems and Data. 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;
- cybersecurity tools to monitor, detect, and respond to threats in real-time;
- the use of external service providers, to assess, test or otherwise assist with certain 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 is designed to escalate certain cybersecurity incidents to members of the management team, depending on the circumstances; 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 management 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 management team also has responsibility for approving budgets, helping prepare for cybersecurity incident responses, and approving cybersecurity processes. 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 an additional office space in Emeryville, California under a lease which ends in August 2028. In January 2025, we also entered into a lease for additional office space in Branchburg, New Jersey which ends in January 2030. 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. The court has most recently set a trial date of July 21, 2025. We dispute the allegations and are vigorously defending 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 is traded under the ticker symbol "CGON" on the Nasdaq Global Select Market.

Holders of Common Stock

As of March 27, 2025, there were approximately 116 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.

Unregistered Sales of Equity Securities

None.

Issuer Repurchases of Equity Securities

None.

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 (IPO). At the closing of our offering on January 29, 2024, we sold 23,000,000 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase 3,000,000 additional shares, at an IPO price of $19.00 per share and received gross proceeds of $437.0 million, which resulted in net proceeds of approximately $399.6 million, after deducting underwriting discounts, commissions of approximately $30.6 million and offering-related transaction costs of approximately $6.8 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates. Morgan Stanley & Co. LLC, Goldman Sachs & Co. LLC and Cantor Fitzgerald & Co. acted as joint-book running managers for the IPO.

The net proceeds from the IPO are held in cash and cash equivalents and marketable securities. Through December 31, 2024, approximately $113.7 million of the net proceeds from the IPO have been used, of which, (i) an estimated $80.5 million was used for research and development costs related to crestostimogene, and (ii) an estimated $33.2 million was used for working capital and general corporate purposes.

There have been no updates to the planned use of proceeds information from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on January 25, 2024. We intend to use the remaining net proceeds from the IPO, together with our existing cash, cash equivalents and marketable securities, to complete the ongoing BOND-003 and CORE-001 clinical trials, complete enrollment for the PIVOT-006 clinical trial, initiate and report topline data for our planned CORE-008 clinical trial, and fund our operations through the submission of a BLA to the FDA for cretostimogene and potentially through the initial commercialization of cretostimogene, if approved, as well as for working capital and other general corporate purposes. We may also use a portion of the net proceeds from the IPO to license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

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 consolidated 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 goal is to develop cretostimogene grenadenorepvec (cretostimogene), our product candidate, as an alternative to BCG in treating a broad range of bladder cancer indications. Cretostimogene, is 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. Given the limitations of currently approved therapies, the next course of treatment for these BCG-unresponsive patients is radical cystectomy, or the complete removal of the bladder, which is associated with significant social, functional and emotional burden. As such, there is a significant unmet need for effective treatments in these patients.

In anticipation of potential FDA approval, we are actively building our commercial operations, marketing, market access and patient access and field force capabilities. This includes pre-launch activities currently being executed, including scientific communication activities and engagements by our field medical organization. We are also implementing strategic initiatives to build seamless product distribution and patient support. Our efforts are focused on ensuring that we are fully prepared to launch and deliver cretostimogene to patients and healthcare providers, if approved. We are evaluating the safety and efficacy of cretostimogene, as a monotherapy, in BOND-003 Cohort C, our ongoing Phase 3 clinical trial in high-risk BCG-unresponsive NMIBC with CIS and with or without Ta/T1 disease. We have completed enrollment for this cohort and reported interim data at the American Urological Association's 2024 Annual Meeting in May 2024, and topline data at the 2024 SUO Annual Meeting in in December 2024, which was updated at the 40th Annual EAU Congress. We believe that this trial could serve as the basis for a BLA submission to the U.S. FDA, which we expect to initiate in the second half of 2025. Cretostimogene has received both Fast Track and Breakthrough Therapy designations from the FDA for the treatment of High-Risk BCG-unresponsive NMIBC with CIS with or without Ta or T1 tumors.

In April 2024, we initiated BOND-003 Cohort P, an exploratory study evaluating cretostimogene monotherapy in high-risk BCG-unresponsive NMIBC with only Ta/T1 disease and expect to report topline data from this Cohort in the second half of 2025. In October 2024, we initiated CORE-008 Cohort A, our Phase 2 clinical trial in high-risk NMIBC patients who are naïve to BCG treatment, including patients with CIS and with or without Ta/T1 disease and patients with only Ta/T1 disease. In March 2025, we expanded CORE-008 into the high-risk BCG-exposed population (Cohort B). We intend to add a third Cohort to CORE-008, evaluating cretostimogene in a combination therapy in the high-risk BCG-exposed population. We have recently completed and published the results for CORE-001, our Phase 2 clinical trial of cretostimogene in combination with pembrolizumab in high-risk BCG-unresponsive NMIBC patients that have CIS. Additionally, in NMIBC that is not categorized as high-risk, we have launched our second Phase 3 clinical trial, PIVOT-006, evaluating adjuvant cretostimogene in intermediate-risk NMIBC following transurethral resection of the bladder tumor (TURBT). We believe cretostimogene, if approved in intermediate-risk NMIBC, has the potential to serve as backbone 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 $88.0 million and $48.6 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $218.0 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 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 common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. 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 $399.6 million, after deducting discounts, commissions and other 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. In December 2024, we completed a follow-on offering of 8,500,000 common shares at a price of $28.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 1,200,000 shares of common stock. We received net proceeds of $223.1 million, after deducting discounts, commissions and other offering expenses.

Through December 31, 2024, we have received aggregate gross proceeds of approximately $982.9 million from the sale of shares of our common stock through public offerings and our redeemable convertible preferred stock. In addition, through December 31, 2024, we have recognized $26.1 million in license and collaboration revenue pursuant to our license and collaboration agreements. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $742.0 million. 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.

We believe, based on our current operating plan, that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. 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.

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. In addition, in June 2024, the Company entered into an additional license agreement with Lepu, under which we granted Lepu a non-exclusive, non-sublicensable, non-transferable license to validate and perform certain assays in the Lepu Territory for the sole purpose of analyzing clinical samples for patients treated with cretostimogene. Under the agreement, Lepu paid us a one-time license fee of $0.4 million. During the years ended December 31, 2024 and 2023, $1.0 million and less than $0.1 million in license and collaboration 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 pay 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, 2024 and 2023, we recorded $0.2 million and $0.2 million, respectively in license and collaboration revenue related to the Kissei License Agreement.

Components of Our Results of Operations

Revenue

Through December 31, 2024, we have recognized $26.1 million in license 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, marketing 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 public offerings.

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, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31, 2024	2023	Change
Revenue:			
License and collaboration revenue	$ 1,139	$ 204	$ 935
Operating expenses:			
Research and development	82,102	45,752	36,350
General and administrative	33,703	9,901	23,802
Total operating expenses	115,805	55,653	60,152
Loss from operations	(114,666)	(55,449)	(59,217)
Other income (expense), net:			
Interest income, net	26,624	6,904	19,720
Other income (expense), net	3	(62)	65
Total other income, net	26,627	6,842	19,785
Net loss and comprehensive loss	$ (88,039)	$ (48,607)	$ (39,432)

License and Collaboration Revenue

License and collaboration revenue was $1.1 million for the year ended December 31, 2024 compared to $0.2 million for the year ended December 31, 2023. During the years ended December 31, 2024 and 2023, we recorded $1.0 million and less than $0.1 million, respectively, in license and collaboration revenue related to the Lepu License Agreement, as well as $0.2 million related to the Kissei License Agreement in both years.

Research and Development Expenses

The following table summarizes our R&D expenses for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31, 2024	2023	Change
External clinical trial expenses	$ 58,052	$ 31,543	$ 26,509
Personnel-related expenses	21,443	12,942	8,501
Other research and development	2,607	1,267	1,340
Total research and development expenses	$ 82,102	$ 45,752	$ 36,350

R&D expenses were $82.1 million for the year ended December 31, 2024 compared to $45.8 million for the year ended December 31, 2023. The increase of $36.4 million in R&D expenses for the year ended December 31, 2024 was primarily due to an increase of $26.5 million in external clinical trial expenses related to higher CRO fees as patient enrollment increased and higher CMC, as well as an increase of $8.5 million in compensation costs due to increased headcount, and higher facilities, fees and other related costs of $1.3 million.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2024	2023	Change
Personnel-related expenses	$ 21,392	$ 5,542	$ 15,850
Professional and consultant fees	6,836	3,170	3,666
Other general and administrative	5,475	1,189	4,286
Total general and administrative expenses	$ 33,703	$ 9,901	$ 23,802

General and administrative expenses were $33.7 million for the year ended December 31, 2024 compared to $9.9 million for the year ended December 31, 2023. The increase of $23.8 million in general and administrative expenses for the year ended December 31, 2024 was primarily due to an increase in compensation costs of $14.9 million due to increased headcount, including a $6.9 million increase in stock-based compensation, as well as increased professional and consultant fees of $3.7 million related to legal, accounting and consulting fees, an increase in marketing-related costs of $2.3 million, and an increase in insurance costs of $1.4 million.

Other Income (Expense), Net

Other income, net, for the year ended December 31, 2024 was a net income of $26.6 million compared to a net income of $6.8 million for the year ended December 31, 2023. For the years ended December 31, 2024 and 2023, other income, net, primarily consisted of $26.6 million and $6.9 million, respectively, in interest income related to marketable securities balances. Marketable securities are higher as of December 31, 2024 due to proceeds from public offerings during the year ended December 31, 2024.

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 common stock through public offerings and our redeemable convertible preferred stock, as well as through previously outstanding term debt. Through December 31, 2024, we have received aggregate gross proceeds of $982.9 million from the sale of shares of our common stock through our public offerings and our redeemable convertible preferred stock. In addition, through December 31, 2024, we have recognized $26.1 million in license and collaboration revenue through our license and collaboration agreements. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $742.0 million. On January 29, 2024, we closed our initial public offering (IPO) of common stock for aggregate net proceeds of $399.6 million, after deducting discounts and commissions and other offering expenses. In December 2024, we closed a follow-on public offering of common stock for aggregated net proceeds of $223.1 million, after deducting discounts and commissions and other 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, 2024 and 2023, we repaid all outstanding principal and accrued and unpaid interest under the loan agreement and have no outstanding debt. See Note 13 to our consolidated 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 consolidated 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, engage in potential strategic transactions, 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 or businesses that we may in-license or acquire.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into the first half of 2028. 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 2026 and 2030. See Note 5 to our consolidated 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, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (78,713)	$ (45,679)
Net cash used in investing activities	(300,764)	(121,195)
Net cash provided by (used in) financing activities	628,279	86,997
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 248,802	$ (79,877)

Operating Activities

During the year ended December 31, 2024, operating activities used $78.7 million of cash, primarily resulting from our net loss of $88.0 million and accretion of the discount on short-term investments of $5.0 million, partially offset by non-cash stock-based compensation charges of $11.4 million and net cash used in changes in our operating assets and liabilities of $2.9 million.

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 and accretion of the discount on short-term investments of $2.9 million, partially offset by net cash used in changes in our operating assets and liabilities of $3.4 million and non-cash stock-based compensation charges of $1.5 million.

Investing Activities

During the year ended December 31, 2024, net cash used in investing activities was $300.8 million, primarily due to purchases of marketable securities and proceeds from sales and maturities of short-term investments.

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.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $628.3 million, consisting primarily of net proceeds from the IPO and follow-on public offering of $403.0 million and $223.1 million, respectively, net of issuance costs and deferred offering costs.

During the year ended December 31, 2023, net cash provided by financing activities was $87.0 million, consisting 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, partially offset by the payments of the term loan of $16.3 million and the deferred offering costs of $3.4 million.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of our consolidated 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 consolidated 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 consolidated 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 consolidated financial statements.

R&D Expenses and Related Prepaid and Accrued Expenses

As part of the process of preparing our consolidated 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 consolidated financial statements included elsewhere in this Annual Report.

Emerging Growth 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 IPO; (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.

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

Not required for a "smaller reporting company" as defined under Item 10(f)(1) of Regulation S-K of the Securities Act.

Item 8. Financial Statements and Supplementary Data.

CG ONCOLOGY, INC.
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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 consolidated balance sheets of CG Oncology, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated 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, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, 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 28, 2025

CG Oncology, Inc.

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

	December 31,	
Assets	**2024**	**2023**
Current assets:		
Cash and cash equivalents	$ 257,068	$ 8,266
Marketable securities	484,930	179,408
Prepaid expenses and other current assets	11,431	6,358
Accounts receivable - other	781	92
Total current assets	754,210	194,124
Property and equipment, net	272	69
Operating lease right-of-use assets	221	422
Other assets	94	19
Deferred offering costs	—	4,667
Total assets	$ 754,797	$ 199,301
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 6,517	$ 3,242
Success fee liability, current portion	—	352
Operating lease liabilities, current portion	186	217
Accrued expenses and other current liabilities	14,665	10,443
Total current liabilities	21,368	14,254
Success fee liability, non-current	—	13
Operating lease liabilities, net of current portion	52	244
Total liabilities	21,420	14,511
Commitments and contingencies (Note 5)		
Redeemable convertible preferred stock:		
Series A-1 redeemable convertible preferred stock, $0.0001 par value per share; zero and 5,075,000 shares authorized, issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; liquidation value of $0 and $3,570 as of December 31, 2024 and December 31, 2023, respectively	—	3,570
Series B redeemable convertible preferred stock, $0.0001 par value per share; zero and 11,973,000 shares authorized, issued and outstanding as of December 31, 2024 and December 31, 2023; liquidation value of $0 and $10,000 as of December 31, 2024 and December 31, 2023, respectively	—	10,000
Series C redeemable convertible preferred stock, $0.0001 par value per share; zero and 73,598,283 shares authorized, issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; liquidation value of $0 and $22,000 as of December 31, 2024 and December 31, 2023, respectively	—	22,000
Series D redeemable convertible preferred stock, $0.0001 par value per share; zero and 53,271,754 shares authorized, issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; liquidation value of $0 and $47,300 as of December 31, 2024 and December 31, 2023, respectively	—	47,300
Series E redeemable convertible preferred stock, $0.0001 par value per share; zero and 112,422,700 shares authorized, issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; liquidation value of $0 and $120,000 as of December 31, 2024 and December 31, 2023, respectively	—	120,000
Series F redeemable convertible preferred stock, $0.0001 par value per share; zero and 81,587,937 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively; liquidation value of zero and $105,020 as of December 31, 2024 and December 31, 2023, respectively	—	105,020
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share; 700,000,000 and 493,530,000 shares authorized as of December 31, 2024 and December 31, 2023, respectively; 76,154,783 and 5,222,283 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	8	—
Additional paid-in capital	951,350	6,842
Accumulated deficit	(217,981)	(129,942)
Total stockholders' equity (deficit)	733,377	(123,100)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 754,797	$ 199,301

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

CG Oncology, Inc.

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

	Year Ended December 31,	
	2024	2023
Revenues		
License and collaboration revenue	$ 1,139	$ 204
Operating expenses		
Research and development	82,102	45,752
General and administrative	33,703	9,901
Total operating expenses	115,805	55,653
Loss from operations	(114,666)	(55,449)
Other income (expense), net:		
Interest income, net	26,624	6,904
Other income (expense), net	3	(62)
Total other income, net	26,627	6,842
Net loss and comprehensive loss	$ (88,039)	$ (48,607)
Deemed dividend on redeemable convertible preferred stock issuances	—	(410)
Cumulative redeemable convertible preferred stock dividends	—	(18,781)
Net loss attributable to common stockholders	$ (88,039)	$ (67,798)
Net loss per share, basic and diluted	$ (1.41)	$ (15.65)
Weighted average shares of common stock outstanding, basic and diluted	62,496,725	4,330,933

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

CG Oncology, Inc.

Consolidated 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' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance as of December 31, 2022	5,075,000	$ 70	11,973,000	$ 000	73,598,283	$ 000	53,271,754	$ 300	112,422,700	$ 00	—	$ —	3,842,694	$ —	$ 3,642	$ (81,335)	$ (77,693)
Issuance of Series F redeemable convertible preferred stock (inclusive of deemed dividend of $410 to accrete to redemption value)	—	—	—	—	—	—	—	—	—	—	81,587,937	105,020	-	$ —	$ (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	$ 70	11,973,000	$ 000	73,598,283	$ 000	53,271,754	$ 300	112,422,700	$ 00	81,587,937	$ 20	5,222,283	$ —	$ 6,842	$ (129,942)	$ (123,100)
Conversion of redeemable convertible preferred stock	(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)	(81,587,937)	(105,020)	38,413,909	4	307,886	—	307,890
Issuance of common stock in connection with an initial public offering, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	23,000,000	3	399,562	—	399,565
Issuance of common stock in connection with a public offering, net of issuance costs	—	—	—	—	—	—	—	—	—	—	—	—	8,500,000	1	223,059	—	223,060
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	—	—	1,018,591	—	2,599	—	2,599
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	11,402	—	11,402
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(88,039)	(88,039)
Balance as of December 31, 2024	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	76,154,783	$ 8	$ 951,350	$ (217,981)	$ 733,377

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

CG Oncology, Inc.

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31, 2024	2023
Operating Activities		
Net loss	$ (88,039)	$ (48,607)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	17
Amortization of loan fees	—	3
Final payment amortization and loss on debt extinguishment	—	767
Success fee amortization	—	37
Stock-based compensation expense	11,402	1,528
Accretion of discount on short-term investments	(4,992)	(2,875)
Non-cash lease expense	(22)	12
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,073)	(2,723)
Accounts receivable - other	(689)	—
Other assets	(75)	13
Accounts payable	3,275	2,012
Accrued expenses and other current liabilities	5,468	4,137
Net cash used in operating activities	(78,713)	(45,679)
Investing Activities		
Proceeds from sales and maturities of short-term investments	745,412	396,416
Purchases of short-term investments	(1,045,942)	(517,611)
Purchases of property and equipment	(234)	—
Net cash used in investing activities	(300,764)	(121,195)
Financing Activities		
Proceeds from initial public offering, net of issuance costs	406,410	—
Proceeds from follow-on public offering, net of issuance costs	223,059	—
Proceeds from issuance of Series F redeemable convertible preferred stock, net of issuance costs	—	104,627
Payments of success fee or long-term debt	(365)	(16,291)
Proceeds from exercise of common stock options and issuance of common stock under the employee stock purchase plan	2,599	2,082
Deferred offering costs	(3,424)	(3,421)
Net cash provided by financing activities	628,279	86,997
Net increase (decrease) in cash and cash equivalents	248,802	(79,877)
Cash and cash equivalents at beginning of period	8,266	88,143
Cash and cash equivalents at end of period	$ 257,068	$ 8,266
Supplemental Disclosure of Cash Flow Information		
Cash paid for interest	$ —	$ 376
Cash paid for taxes	$ —	$ —
Supplemental Schedule of Non-cash Investing and Financing Activities:		
Reclassification of 38,413,909 redeemable convertible preferred stock to 38,413,909 shares of common stock	$ 307,890	$ —
Conversion of deferred offering costs	$ 6,845	$ —
Deferred offering costs, unpaid and accrued	$ —	$ 1,246
Operating lease right-of-use asset obtained in exchange for lease liabilities	$ —	$ 221

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

CG Oncology, Inc.
Notes to Consolidated Financial Statements

1. Description of Business and Basis of Presentation

Description of Business

CG Oncology, Inc. (the Company) is a late-stage clinical biopharmaceutical company focused on developing and commercializing its product candidate, cretostimogene grenadenorepvec, 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. FDA approves its product candidate, cretostimogene, and the Company is able to commercialize this product candidate.

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 consolidated 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 conversion ratios for each series of the Company's redeemable convertible preferred stock and the shares of common stock underlying outstanding stock options and other equity instruments were all proportionately adjusted, as needed.

On January 29, 2024, the Company completed the closing of its IPO 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 $399.6 million, after deducting discounts and commissions and other offering expenses. In addition, as a result of its IPO, the Company's redeemable convertible preferred stock converted into common stock concurrently with the IPO. In December 2024, we completed a follow-on offering of 8,500,000 common shares at a price of $28.00 per share, including the exercise in full by the underwriters of their option to purchase an additional 1,200,000 shares of common stock. We received net proceeds of $223.1 million, after deducting discounts, commissions and other offering expenses.

Basis of Presentation

The accompanying consolidated 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, 2024, the Company had approximately $742.0 million of cash, cash equivalents and marketable securities and working capital of approximately $732.8 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, 2024, the Company had an accumulated deficit of $218.0 million. During the year ended December 31, 2024, the Company incurred a net loss of $88.0 million and negative cash flows from operations of $78.7 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, 2024, the Company has funded its operations primarily with proceeds from the sale of common shares from its public offerings, 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 consolidated 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 consolidated 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 consolidated financial statements including stock-based compensation expense, accrued research and development 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. Actual results could differ materially from the estimates and assumptions used in the preparation of the accompanying consolidated 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, 2024 and 2023. 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, 2024 and 2023.

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, 2024 and 2023.

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 IPO. The deferred offering costs was offset against the IPO proceeds upon the consummation of an offering. As of December 31, 2024 and 2023, respectively, the Company had zero and $4.7 million 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, 2024 and 2023.

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.

Revenue Recognition

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

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. For any performance-based awards, the Company assesses the probability of the likelihood of achievement and recognizes the related expense accordingly.

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 consolidated 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 12 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 IRS 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, including the conversion of all redeemable convertible preferred stock as of December 31, 2024.

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. See Note 7 for additional information.

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 consolidated 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. The Company adopted this standard for the year ended December 31, 2024 and applied the amendments retrospectively to all periods presented in the consolidated financial statements. See our segments disclosure in Note 7 for further detail.

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 consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, Comprehensive Income - Expense Disaggregation Disclosures , which will improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses in commonly presented expense captions such as cost of sales, selling, general and administrative, and research and development. The amendments are effective for fiscal years beginning after December 15, 2026. Early adoption is permitted for annual financial statements that have not yet been issued or made available. The amendments should be applied on either (1) prospectively to financial statements issued for reporting periods after the effective date or (2) retrospectively to any or all prior periods presented in the financial statements. The Company is currently evaluating the provisions of the amendments and the effect on its future consolidated 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, 2024 and 2023 in accordance with the ASC 820, *Fair Value Measurement* (ASC 820) hierarchy (in thousands):

	Fair Value Measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 256,204	$ —	$ —	$ 256,204
Marketable securities	$ —	$ 484,930	$ —	$ 484,930

	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

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 13 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, 2024 and 2023, however, subsequent to December 31, 2024, the Company committed approximately $25 million of its cash equivalents to long-term use.

4.Accrued Expenses and Other Current Liabilities

The components of accrued expenses and other current liabilities for the years ended December 31, 2024 and 2023 were as follows (in thousands):

	December 31, 2024	December 31, 2023
External research and development expenses	$ 7,181	$ 6,164
Personnel-related expenses	5,793	2,822
Professional fees	1,255	341
Deferred offering costs	—	1,017
Other	436	99
Total accrued expenses and other current liabilities	$ 14,665	$ 10,443

5.Commitments and Contingencies

Operating Leases

On January 1, 2019, the Company adopted ASC 842, *Leases*. As of December 31, 2024 and 2023, the Company had two operating leases, in which the Company is the lessee for office space. As of December 31, 2024, the lease terms were through 2025 and 2026. The Company had no finance leases as of December 31, 2024 and 2023.

The components of lease expense for the years ended December 31, 2024 and 2023 were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Lease cost		
Operating lease cost	$ 228	$ 232
Total lease cost	$ 228	$ 232
Other information		
Operating lease right-of-use asset obtained in exchange for new operating lease liabilities	$ —	$ 221
Cash paid for amounts included in the measurement of lease liabilities, included in operating cash flows	$ 223	$ 219
Weighted-average remaining lease term	1.20	2.11
Weighted-average discount rate	1.63%	1.63%

Maturities of lease liabilities as of December 31, 2024 were as follows (in thousands):

2025	$ 187
2026	52
Total lease payment	239
Less: amount representing imputed interest	(1)
Total future minimum lease obligations	$ 238

Legal Proceedings

A liability for loss contingencies arising from claims, assessments, litigation, fines, penalties, and other sources is recorded in the consolidated 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 court set a trial date for July 21, 2025. The Company disputes the allegations and is vigorously defending 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, 2024 and 2023, 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, 2024 and 2023, $1.0 million and less than $0.1 million in collaboration and license fee 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, 2024 and 2023, the Company recorded $0.2 million in development income related to the Kissei License Agreement.

7.Segment Disclosures

The Company operates as a single operating segment. The Company's chief operating decision maker (CODM) is its chief executive officer, who reviews financial information presented on a consolidated basis. The CODM uses consolidated net income (loss) to assess financial performance and allocate resources. The CODM does not review assets in evaluating the results of the single segment and therefore, such information is not presented.

The following table presents selected financial information with respect to the Company's single operating segment for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Revenue	$ 1,139	$ 204
Less:		
Research and development		
Clinical and manufacturing	66,462	35,966
Other research and development[(1)]	15,640	9,786
Total research and development	82,102	45,752
General and administrative	33,703	9,901
Total operating expenses	115,805	55,653
Loss from operations	(114,666)	(55,449)
Other income, net	26,627	6,842
Net loss	$ (88,039)	$ (48,607)

(1) Other research and development consists of indirect costs incurred for the benefit of the research and development efforts, including certain personnel, supply chain, and quality assurance.

8.Redeemable Convertible Preferred Stock

As of December 31, 2024, the Company has no outstanding redeemable convertible preferred stock as all redeemable convertible preferred stock converted into common stock concurrently with the IPO in January 2024.

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 years ended December 31, 2024 and 2023.

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.

9.Common Stock

The Company is authorized to issue up to 700,000,000 and 493,530,000 shares of common stock as of December 31, 2024 and 2023, respectively, of which 76,154,783 and 5,222,283 shares were issued and outstanding as of December 31, 2024 and 2023, respectively.

Voting, dividend and liquidation rights of the holders of the common stock as of December 31, 2023 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, 2024, 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, 2024
Stock options outstanding	6,574,580
Reserved for future stock option issuances	6,222,990
Reserved for future ESPP issuances	783,096
Total	13,580,666

10.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. As of December 31, 2024, there were 921,231 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. As of December 31, 2024, there were 3,356,572 shares of common stock subject to outstanding awards under the 2022 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 with respect to its IPO was declared effective by the SEC. The 2024 Plan replaced the 2022 Plan, 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 (1) 8,246,565 shares, plus (2) 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. As of December 31, 2024, there were 2,296,777 shares of common stock subject to outstanding awards and 6,222,985 shares of common stock remaining and available for issuance under the 2024 Plan.

The Company may grant options to purchase authorized but unissued shares of the Company's common stock. Options granted under the 2015 Plan, 2022 Plan and 2024 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, 2022 Plan and 2024 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, 2022 Plan and 2024 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, 2024 and 2023:

	Year Ended December 31,	
	2024	**2023**
Expected volatility	77.34% - 84.50%	81.6%
Risk-free interest rate	3.46% - 4.62%	3.58% - 4.77%
Expected dividend yield	0%	0%
Expected term (in years)	6.0 - 6.1	6.0

The weighted-average grant-date fair value of the options granted was $22.53 and $4.27 per share for the years ended December 31, 2024 and 2023, respectively. The fair value of shares vested during the years ended December 31, 2024 and 2023 was $5.90 and $2.41 per share, respectively. The fair value of shares exercised during the years ended December 31, 2024 and 2023 was $2.16 and $1.43 per share, respectively.

The following table summarizes stock option activity for the year ended December 31, 2024 (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, 2023	5,532,871	$ 4.12	8.55	$ 40,290
Granted	2,310,258	$ 32.17		
Exercised	(989,445)	$ 2.16		
Forfeited/Expired	(279,104)	$ 6.06		
Balance at December 31, 2024	6,574,580	$ 14.19	8.20	$ 108,155
Vested and expected to vest at December 31, 2024	6,574,580	$ 14.19	8.20	$ 108,155
Exercisable at December 31, 2024	2,069,984	$ 4.56	6.61	$ 50,494

The Company has recorded stock-based compensation expense related to stock options of $9.5 million and $1.5 million for the years ended December 31, 2024 and 2023, respectively. The Company had an aggregate $55.4 million of gross unrecognized stock-based compensation expense as of December 31, 2024 remaining to be amortized over a weighted-average period of 3.35 years.

Stock-based compensation expense related to stock options recorded in the accompanying statements of operations for the years ended December 31, 2024 and 2023 was as follows (in thousands):

	For the Year Ended December 31,	
	2024	2023
Research and development	$ 3,736	$ 795
General and administrative	7,666	733
Total stock-based compensation expense	$ 11,402	$ 1,528

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.

11. Employee Stock Purchase Plan

On January 11, 2024, the Company's board of directors and stockholders approved the 2024 Employee Stock Purchase Plan (the ESPP), which became effective on the date on which the Company's registration statement with respect to its IPO was declared effective by the SEC. The number of shares initially available for issuance pursuant to the ESPP is 812,242 shares. The ESPP provides for the sale of the Company's common stock to eligible employees at 85% of the fair market value of the Company's common stock at the commencement date of each offering period or the relevant date of purchase, whichever is lower. Payroll deductions are limited to 15% of the employee's eligible compensation, subject to IRS limits. In addition, employees may not buy more than 100,000 shares during any purchase period or offering period. There were 29,146 shares purchased under the ESPP during the year ended December 31, 2024. As of December 31, 2024, there were approximately 0.8 million shares available for issuance under the ESPP.

The Company recorded stock-based compensation expense under the ESPP of approximately $1.9 million for the year ended December 31, 2024. As of December 31, 2024, the Company had $2.7 million of gross unrecognized stock-based compensation expense under the ESPP to be recognized over a weighted average period of 1.18 years.

12.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, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Income tax computed at federal statutory rate	21.00%	21.00%
State taxes, net of federal benefit	(0.00)	(0.00)
Permanent differences	(0.62)	(0.64)
Stock-based compensation	6.18	(0.20)
Research and development credit	2.64	2.97
Other	0.27	0.59
Valuation allowance	(29.47)	(23.72)
Effective income tax rate	0.00%	(0.00%)

The Company's deferred tax assets as of December 31, 2024 and 2023, consisted of the following (in thousands):

	Year Ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating losses	$ 34,612	$ 18,015
R&D credit	6,946	4,756
Foreign tax credit	425	424
Operating lease liabilities	50	97
Section 174	12,536	6,998
Other	1,884	266
Total gross deferred tax assets	56,453	30,556
Deferred tax liabilities:		
Operating lease right-of-use assets	(46)	(89)
Other	(5)	(10)
Total gross deferred tax liabilities	(51)	(99)
Net deferred tax assets	56,402	30,457
Valuation allowance	(56,402)	(30,457)
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, 2024, the valuation allowance for deferred tax assets increased by $25.9 million. This increase was primarily related to the establishment of a valuation allowance against additional net operating loss (NOL), Section 174 capitalized research and experimental (R&E) costs and research credits generated in the current year.

As of December 31, 2024, the Company calculated $166.4 million and $0.2 million of federal and state NOL carryforwards, respectively. Of the $166.4 million in federal NOL carryforwards, $154.2 million is not subject to expiration and the other $12.3 million begin to expire in 2030. The state NOL carryforwards begin to expire in 2040. In addition, as of December 31, 2024, the Company had $7.7 million of federal research and development (R&D) credit carryovers which begin to expire in 2030 and $1.4 million of California credit carryovers, which can be carried forward indefinitely. There is also $0.1 million of Texas credit generated in 2024 that can be carried forward for twenty years. 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 utilization of the NOL carryforwards would be subject to an annual limitation under Section 382 of the Code. Any limitation may result in expiration of a portion of the NOL carryforwards before utilization.

As of December 31, 2024 and 2023, the Company recorded $1.4 million and $1.0 million unrecognized tax benefits, respectively. 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, 2024 and 2023, no estimated interest or penalties were recognized on uncertain tax positions, and as of December 31, 2024 the Company has not incurred any material interest or penalties as of the current reporting date with respect to income tax matters.

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,	
	2024	2023
Beginning balance of unrecognized tax benefits	$ 1,000	$ 691
Additions for prior year tax positions	(12)	53
Additions for current year tax positions	409	256
Ending balance of unrecognized tax benefits	$ 1,397	$ 1,000

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.

Tax Cuts and Jobs Act's (TCJA) amendment to Section 174 required 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, creating a significant first year impact.

13.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 were not to exceed $5.0 million, in increments of $2.5 million each, were not drawn upon in 2021 or in 2022 and were 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.

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 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.

The Company had 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.

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. On March 5, 2024, the Company paid $0.4 million for the success fee under the Success Fee Agreement. As of December 31, 2024, the Company has no outstanding obligations in connection with the Loan Agreement with SVB.

14.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,	
	2024	2023
Numerator:		
Net loss and comprehensive loss	$ (88,039)	$ (48,607)
Deemed dividend on redeemable convertible preferred stock issuances	—	(410)
Cumulative redeemable convertible preferred stock dividends	—	(18,781)
Net loss attributable to common stockholders	$ (88,039)	$ (67,798)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	62,496,725	4,330,933
Net loss per share attributable to common stockholders, basic and diluted	$ (1.41)	$ (15.65)

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, 2024 and 2023 because including them would have had an anti-dilutive effect:

	December 31,	
	2024	2023
Conversion of redeemable convertible preferred stock	-	38,413,913
Stock options outstanding	6,574,580	5,532,871
Total	6,574,580	43,946,784

15.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 $0.1 million and $0.4 million, respectively for services rendered for the years ended December 31, 2024 and 2023.

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, has 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

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). We maintain internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, in designing and evaluating the disclosure controls and procedures, management recognizes that any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

As of December 31, 2024, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on management's assessment, management has concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

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, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Trading Arrangements

During the quarter ended December 31, 2024, an entity affiliated with one of our directors terminated a trading plan for the orderly disposition of the Company's securities as set forth in the table below.

			Type of Trading Arrangement			
Name and Position	**Action**	**Adoption/Termination Date**	**Rule 10b5-1[(1)]**	**Non-Rule 10b5-1[(2)]**	**Total Shares of Common Stock to be Sold**	**Expiration Date**
Charming Jade Limited*	Termination[(3)]	December 13, 2024	X		1,266,814	The earlier to occur of (i) June 11, 2025, and (ii) the execution of all instructions provided in the plan

[(1)] Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

[(2)] "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

[(3)] Represents the termination of a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) adopted on September 13, 2024.

* 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 a wholly owned subsidiary of ORI Holding II Inc. Each of ORI Capital Holding Inc. and ORI Holding II Inc. is a wholly owned subsidiary of Healthcare Seed Limited. Ms. Hong Fang Song, who serves on our Board of Directors, is the sole owner of Healthcare Seed Limited.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item (other than as set forth below) will be contained in our Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2024, and is incorporated herein by reference.

We have adopted a Code of Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. A current copy of the Code of Conduct and Ethics is available on the Corporate Governance section of our website at ir.cgooncology.com. If we make any substantive amendments to the Code of Conduct and Ethics or grants any waiver from a provision of the Code of Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item will be contained in the Proxy Statement under the headings "Executive Compensation" and "Non-Employee Director Compensation," and is incorporated herein by reference.

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

The information required by this item will be contained in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans," and is incorporated herein by reference.

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

The information required by this item will be contained in the Proxy Statement under the headings "Certain Relationships and Related Person Transactions" and "The Board of Directors and Certain Governance Matters," and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be contained in the Proxy Statement under the heading "Ratification of Appointment of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

1.Financial Statements.

See "Index to Consolidated Financial Statements" under Part II, Item 8 to this Annual Report on Form 10-K.

2.Finance Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the consolidated 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	10-K	03/26/24	4.3	
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#	Amended and Restated Non-Employee Director Compensation Program				X
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	
10.11#	Amended and Restated Employment Agreement, effective January 9, 2025, between Arthur Kuan and the Registrant				X
10.12#	Amended and Restated Employment Agreement, effective January 9, 2025, between Ambaw Bellete and the Registrant				X
10.13#	Amended and Restated Employment Agreement, effective January 9, 2025, between Vijay Kasturi and the Registrant				X
10.14#	Amended and Restated Employment Agreement, effective January 9, 2025, between Corleen Roche and the Registrant				X

10.15#	Amended and Restated Employment Agreement, effective January 9, 2025, between Joshua F. Patterson and the Registrant				X
19.1	Insider Trading Policy				X
21.1	Subsidiaries of the Registrant				X
23.1	Consent of Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (see signature page)				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	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Document.				X
104	Cover page formatted as Inline XBRL and contained in Exhibit 101				X

# Indicates management contract or compensatory plan.
* This certification is deemed not filed for purposes 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 28, 2025

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Arthur Kuan and Corleen Roche, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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 28, 2025
/s/ Corleen Roche **Corleen Roche**	Chief Financial Officer (principal financial and accounting officer)	March 28, 2025
/s/ Susan Graf **Susan Graf**	Director	March 28, 2025
/s/ Brian Liu, M.D. **Brian Liu, M.D.**	Director	March 28, 2025
/s/ James J. Mulé, IPh.D. **James J. Mulé, IPh.D.**	Director	March 28, 2025
/s/ Leonard Post, Ph.D. **Leonard Post, Ph.D.**	Director	March 28, 2025
/s Simone Song **Simone Song**	Director	March 28, 2025
/s/ Victor Tong, Jr. **Victor Tong, Jr.**	Director	March 28, 2025