UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2025

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: 001-37798

Cartesian Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-1622110**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
7495 New Horizon Way, Frederick, MD	**21703**
(Address of principal executive offices)	**(Zip Code)**

(301) 348-8698
Registrant's telephone number, including area code

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	RNAC	The Nasdaq Stock Market LLC

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

Title of each class
Contingent Value Rights

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 Section 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 and post such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 attested to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

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

The aggregate market value of common stock held by non-affiliates of the registrant based on the closing price of the registrant's common stock as reported on the Nasdaq Stock Market on June 30, 2025, the last business day of the registrant's most recently completed second quarter, was $108,739,558.

As of February 28, 2026, the registrant had 26,509,024 shares of common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2026 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or the Annual Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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, prospective products, product approvals, research and development costs, timing and likelihood of success, the plans and objectives of management for future operations and future results of anticipated products, and the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "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 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 important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the sections in this Annual Report titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as the following:

- our future results of operations and financial position, business strategy, and the length of time that we believe our existing cash resources will fund our operations;
- our market size and our potential growth opportunities;
- our preclinical and clinical development activities;
- our dependence on third-parties, including contract research organizations, or CROs, in the conduct of our pre-clinical studies and clinical trials;
- the efficacy and safety profile of our product candidates;
- the potential therapeutic benefits and economic value of our product candidates;
- the timing and results of preclinical studies and clinical trials;
- the potential impairment of our goodwill and indefinite lived intangible assets;
- the expected impact of macroeconomic conditions, including inflation, increasing interest rates and volatile market conditions, current or potential bank failures;
- the impact of global events, including the ongoing conflicts between Russia and Ukraine, the ongoing conflict in the Middle East and geopolitical tensions with China;
- the impact of political uncertainty on our product development;
- the receipt and timing of potential regulatory designations, approvals and commercialization of our product candidates;
- our ability to prevent or minimize the effects of litigation and other contingencies;
- our status as a development-stage company and our expectation to incur losses in the future, and the possibility that we never achieve or maintain profitability;
- uncertainties with respect to our ability to access future capital;
- our ability to maximize the value of our pipeline of product candidates;
- our unproven approach to therapeutic intervention;
- our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;

- our ability to continue to grow our manufacturing capabilities and resources;
- our ability to manufacture our product candidates, which in some cases are manufactured on a patient-by-patient basis;
- our ability to receive or manufacture sufficient quantities of our product candidates;
- our ability to maintain our existing or future collaborations or licenses and to seek new collaborations, licenses or partnerships;
- our ability to protect and enforce our intellectual property rights;
- federal, state, and foreign regulatory requirements, including U.S. Food and Drug Administration, or FDA, regulation of our product candidates;
- our ability to obtain and retain key executives and retain qualified personnel:
- developments relating to our competitors and our industry:
- any future payouts under the contingent value right, or CVR, issued to our holders of record as of the close of business on December 4, 2023; and
- our ability to monetize any of our legacy assets.

Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risk and uncertainties.

You should read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan 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.

PART I

Item 1. Business

Our Corporate History and Background

The Company (formerly known as Selecta Biosciences, Inc., or Selecta) was incorporated in Delaware on December 10, 2007, and is headquartered in Frederick, Maryland. On November 13, 2023, the Company and the Delaware corporation which, immediately prior to the Merger (as defined below), was known as Cartesian Therapeutics, Inc., or Old Cartesian, entered into an Agreement and Plan of Merger, or the Merger Agreement, by and among the Company, Sakura Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, or First Merger Sub, Sakura Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, or Second Merger Sub, and Old Cartesian. Pursuant to the Merger Agreement, and simultaneously with execution thereof, (i) First Merger Sub merged with and into Old Cartesian, pursuant to which Old Cartesian was the surviving corporation, or the First Step Surviving Corporation, and became a wholly owned subsidiary of the Company, or the First Merger, and (ii) immediately following the First Merger, Old Cartesian (as the First Step Surviving Corporation) merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving company, or the Surviving Company, and continued under the name "Cartesian Bio, LLC", or the Second Merger and, together with the First Merger, the Merger. In connection with the Merger and pursuant to the Merger Agreement, the Company (which was known as Selecta Biosciences, Inc. until immediately prior to the Merger) changed its corporate name to Cartesian Therapeutics, Inc.

Overview

We are a late clinical-stage biotechnology company pioneering cell therapy for the treatment of autoimmune diseases. We leverage our proprietary technology and manufacturing platform to introduce mRNA into cells to provide a therapeutic effect to patients suffering from a variety of autoimmune conditions. Unlike DNA, mRNA degrades naturally over time without integrating into the cell's genetic material. Our cell therapies are designed to be dosed repeatedly like conventional drugs, administered in an outpatient setting and given without pre-treatment chemotherapy required with many conventional cell therapies.

Autoimmune diseases, where the immune system mistakenly attacks the body, are a family of more than 80 disorders. These diseases are typically treated with immunosuppressant medications, such as steroids, biologics and non-steroidal agents such as methotrexate, CD19 directed therapies and intravenous immunoglobulin. These treatments must be administered chronically and carry risks, including infection, osteoporosis and metabolic disease. The treatment landscape within generalized myasthenia gravis, or MG, offers agents that block the complement pathway or inhibit the neonatal Fc receptor, or FcRn, that typically must be administered chronically. Even with recent treatment advancements in the field of MG, we believe there remains a significant unmet need for outpatient treatments, administered over a short period of time, and can provide deep and durable clinical benefit.

Limitations of Current Biologic Treatments in Autoimmune Disease

Currently approved biologic therapies for MG, such as complement inhibitors and FcRn inhibitors have improved treatment options. However, these therapies are still limited by incomplete response, chronic dosing required to mitigate symptoms, immunosuppression risks, high treatment burden and lack of disease modification.

Not all patients with acetylcholine receptor autoantibody positive, or AChR+ MG, the subtype currently being pursued in our Phase 3 AURORA trial, respond adequately to currently approved biologics. We believe the variability in treatment response may be due to differences in underlying disease pathologies, with some patients having disease drivers beyond complement activation (for complement inhibitors) or immunoglobulin G, or IgG, reduction (for FcRn inhibitors). Additionally, some patients experience an initial improvement but later lose response, requiring adjustments in their treatment strategy.

Biologic therapies used for MG can increase the risk of infections. Complement inhibitors in particular, heighten susceptibility to Neisseria infections, necessitating vaccination and, in some cases, prophylactic antibiotic use. Patients receiving FcRn inhibitors may also experience an increased risk of infections due to immunoglobulin depletion. The long-term safety of these treatments remain an area of active study.

Currently approved biologic therapies require frequent infusions, which can be burdensome for patients. Efgartigimod (Vyvgart) and rozanolixizumab (Rystiggo) both require weekly infusions in repeated cycles, while zilucoplan (Zilbrysq) is administered daily, both nipocalimab-aahu (Imaavy) and eculizumab (Soliris) are administered every two weeks, ravulizumab (Ultomiris) every eight weeks for most body weights and inebilizumab-cdon (Uplizna) every six months following two initial doses. While ravulizumab and inebilizumab-cdon each reduce the frequency of infusions compared to eculizumab, both of these

treatments require ongoing maintenance, which may impact patient quality of life. Access to infusion centers or home infusion services further adds to the logistical challenges.

The majority of approved biologic therapies for the treatment of MG focus on the management of symptoms rather than addressing the root cause of the disease. These treatments do not eliminate the underlying autoimmune process or autoreactive B and T cells, meaning patients typically require chronic lifelong therapy. While symptom control is critical, the need for continuous treatment highlights the unmet need for therapies that can induce long-term remission and a precision immune reset.

Limitations of Current DNA-Based Cell Therapy Treatments in Autoimmune Disease

Compared to biologic therapies, cell therapies have increased potential to provide a deep and durable clinical benefit; however, conventional DNA cell therapies have been associated with cytokine release syndrome, or CRS, neurological toxicities and Parkinsonism, infection, risk of secondary malignancy and death. The acute toxicities are from exponential amplification of the modified cell and the pre-treatment chemotherapy administered to enable cell amplification.

Conventional DNA-engineered chimeric antigen receptor, or CAR, T-cells are in clinical development for several autoimmune diseases. DNA CAR-T cells are typically administered to patients in a subtherapeutic dose, which means that the cells must proliferate to reach therapeutic numbers in the body. However, this proliferation is not controlled in magnitude nor duration, varies from patient to patient, and can be unpredictable. This proliferation occurs because the CAR gene is irreversibly integrated into the T-cell's genome, causing a cascade in which every daughter cell carries the same CAR as the parent cells. The resulting unconstrained proliferation frequently exceeds the toxicity threshold, leading to serious adverse events, or SAEs.

The proliferation of DNA CAR-T cells typically requires pre-treatment chemotherapy, usually fludarabine and cyclophosphamide, administered for several days before CAR-T cell treatment. This chemotherapy is toxic, suppressing the immune system and increasing the risk of infection, anemia, and neurotoxicity.

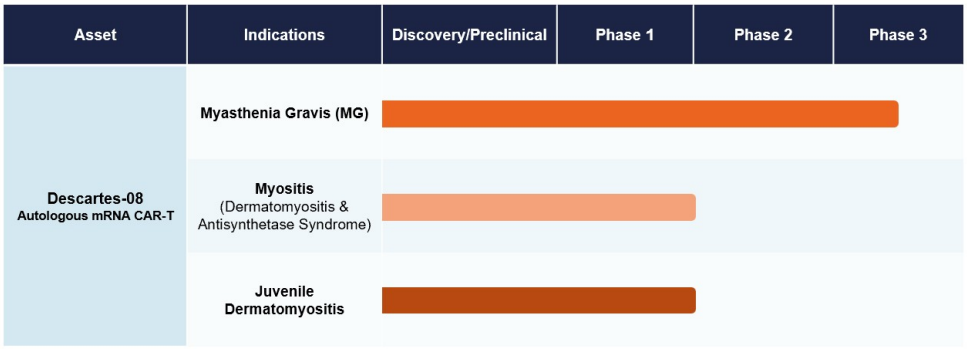
Given these risks and requirements, conventional DNA cell therapies are administered under close monitoring in an inpatient setting, increasing their cost and limiting their reach to only the sickest patients.

Our Autoimmune Disease Solution

Descartes-08, our lead cell therapy product candidate, is an autologous CAR-T product targeting B-cell maturation antigen, or BCMA, in clinical development for the treatment of MG and myositis, specifically, moderate to severe multi-refractory dermatomyositis and antisynthetase syndrome. In contrast to conventional DNA-based CAR T-cell therapies, our CAR-T administration has been observed to provide deep and durable benefits through 12 months, is designed to not require preconditioning chemotherapy, to be administered in the outpatient setting and does not carry the risk of genomic integration associated with cancerous transformation. Descartes-08 has been granted Orphan Drug Designation and Regenerative Medicine Advanced Therapy, or RMAT, Designation by the FDA for the treatment of MG, and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis, or JDM.

Based on efficacy and safety data observed in our clinical trials thus far, we believe our cell therapies have the potential to deliver deep and durable clinical benefit to a broad group of patients with autoimmune diseases after a single course of therapy. We aim to provide a personalized approach to treating patients that begins with the collection of a patient's cells which we then use to manufacture our cell therapy product candidates. Once a patient's cells have expanded in our process, we introduce mRNA to deliver a CAR into the cell. Once the manufacturing process is complete, we send the product candidate back to the treating physician where they administer six weekly infusions of our cell therapy to the patient. Descartes-08 is specifically designed to target and destroy the pathogenic, self-reactive cells that are the underlying cause of the autoimmune disease, with the goal of creating a precision immune reset for the patient.

The table below summarizes key information about our development pipeline.



As of December 31, 2025, we have administered Descartes-08 to over 100 patients suffering from one of MG, multiple myeloma, and other diseases in open-label and randomized placebo-controlled trials on an outpatient basis. We have not observed product-related CRS, neurotoxicity or infection of any grade. The most common product-related adverse events, or AEs, observed, headache, nausea, and fever, were self-limited and resolved within 24 hours of onset.

Our Product Candidates

Descartes-08 for the Treatment of MG

Overview

Descartes-08 has been granted Orphan Drug Designation by the FDA for the treatment of MG. We chose MG as our lead indication because the pathogenesis for MG is common to many autoimmune diseases.

Background Information About MG

MG is a rare autoimmune disease that causes debilitating muscle weakness and fatigue. It is estimated to affect over 106,000 patients in the U.S. MG patients develop antibodies that lead to an immunological attack on critical signaling proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. This results in muscle weakness in tissues throughout the body, potentially manifesting in partial paralysis of eye movements, problems in chewing and swallowing, respiratory problems, speech difficulties and weakness in skeletal muscles. As the disease progresses, symptom-free periods become less frequent and disease exacerbations can last for months. Disease symptoms reach their maximum levels within two to three years in approximately 80% of patients. Up to 20% of MG patients experience a respiratory crisis at least once in their lives. During the crisis phase, decline in respiratory function can become life-threatening. Patients in crisis often require intubation and mechanical ventilation.

There are no known cures for MG and the current standard of care consists of chronic use of steroids and other immunosuppressants. These treatments must be administered continually and carry risks such as infection, osteoporosis, and metabolic diseases. Newer agents, such as those that block the complement pathway or inhibit FcRn, are typically administered continually.

Clinical Development

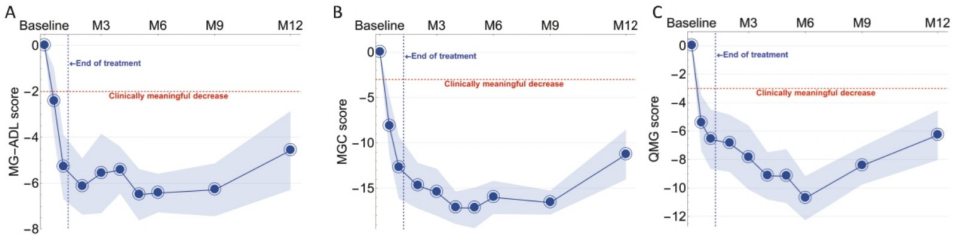
To date, we have completed a Phase 1/2 trial of Descartes-08 in MG, which consisted of a Phase 1b portion, a Phase 2a portion, and a Phase 2b portion.

The primary objective of the Phase 1b portion of the trial was to determine the maximum tolerated dose of Descartes-08 for patients with MG. We observed Descartes-08 to be well-tolerated by the three patients who participated in this portion of the trial with no CRS or other serious product-related AEs observed.

The primary objective of the Phase 2a portion of the trial was to determine the optimal dosing schedule for patients with MG using the highest dose level tested in Phase 1b (52.5 x106 cells/kg). This portion of the trial was designed to assess the safety and preliminary efficacy of Descartes-08 when administered across three different treatment schedules (six doses given twice-weekly, once-weekly, or once-monthly). This portion of the trial evaluated 11 patients with particularly advanced disease

as assessed by both patient and clinician-reported outcomes. 11 of the 14 patients included in the Phase 1b and Phase 2a portions of the trial were classified at screening to have Class III or IV disease, as defined by the Myasthenia Gravis Foundation of America, indicating they had moderate-to-severe weakness affecting their muscles.

The results of the Phase 2a portion of the trial, published in the Lancet Neurology in July 2023, indicated that after six weekly infusions of Descartes-08, the average improvement in all disease severity scores was three-to-five-fold greater than what is considered clinically meaningful by expert consensus. As shown in the figure below, clinical improvements persisted in all patients at Month 9, and in five of the seven remaining patients at a final, 12-month follow-up. Descartes-08 was observed to be well-tolerated with no reports of dose-limiting toxicities, CRS or neurotoxicity.



A–C: Mean change from Baseline (line) and standard error (bands) in Myasthenia Gravis Activities of Daily Living Score (MG-ADL, A), Quantitative Myasthenia Gravis Score (QMG, B), Myasthenia Gravis Composite Score (MGC, C) during 12 months of follow-up for MG-001 participants who received six once-weekly doses (n=7). MG-ADL is self-reported; MGC and QMG are neurologist-assessed.

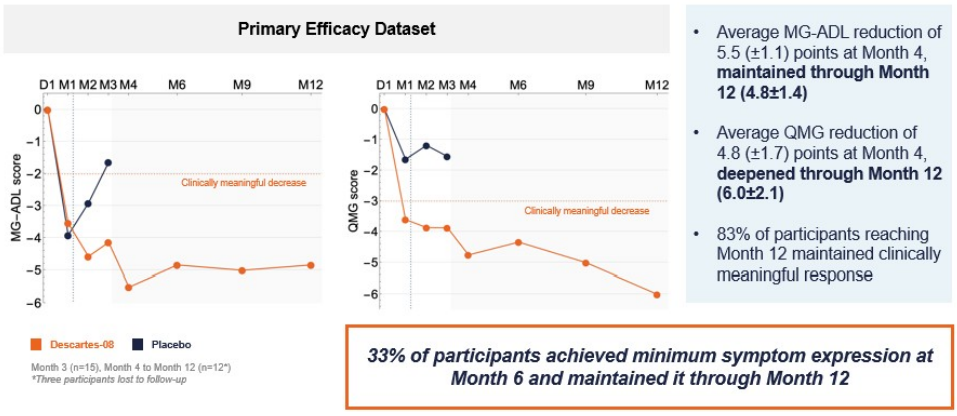
All three participants with detectable anti-acetylcholine receptor antibody levels before treatment had an average 42% reduction in antibody levels by Month 6. These reductions deepened to 68% by Month 9 and persisted at Month 12. In summary, we observed continued clinical improvement and autoantibody reductions after BCMA directed mRNA CAR-T treatment for MG that persisted through the one-year follow-up period.

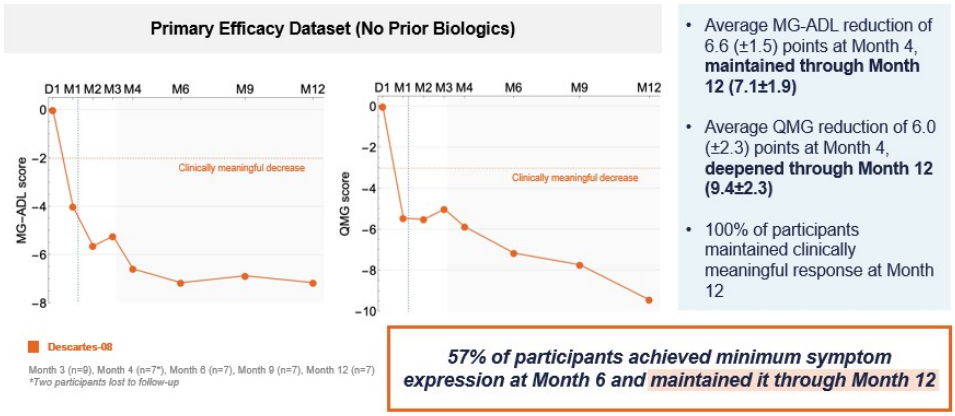
Follow-on results of the Phase 2b portion of the trial were presented in December 2024. The trial achieved its primary endpoint to assess the proportion of patients achieving a five-point or greater reduction in their MGC score at day 85. Patients received six weekly infusions at the dose established in Phase 1b (52.5 x106 cells/kg). The trial also involved a crossover component in which any patient originally assigned to placebo was given the opportunity to receive Descartes-08 after completing trial treatment.

In April, 2025, we reported updated, 12-month data from this trial and published this data in *Nature Medicine* in January 2026.

Deepening of responses was observed over time with participants included in the primary efficacy dataset who continued follow-up (n=12) experiencing an average MG-ADL reduction of 5.5 (±1.1) at Month 4 which was maintained through Month 12 (4.8±1.4). At Month 4, particularly deep responses were observed in participants without prior exposure to biologic therapies (n=7), including complement or neonatal fragment crystallizable receptor inhibitors, with an average MG-ADL reduction of 6.6 (±1.5). Responses amongst this patient population without prior exposure to biologic therapies were observed to deepen through Month 12 with an average MG-ADL reduction of 7.1 (±1.9). The deepest responses were observed as minimal symptom expression, or MSE, defined as an MG-ADL score of 0 or 1.

The tables below set forth the results observed.





33% (4/12) of participants in the primary efficacy dataset and 57% (4/7) of participants with no prior exposure to biologic therapy were observed to achieve MSE by Month 6 and maintained it through Month 12. Responses were observed to be durable through Month 12, with 83% (10/12) of evaluable participants from the primary efficacy dataset maintaining a clinically meaningful response, defined as a reduction in MG-ADL score of at least 2 points. Of the seven participants with no prior exposure to biologic therapy that reached Month 12, 100% maintained at least a clinically meaningful response.

The safety profile observed in the follow-up portion of the Phase 2b trial was in line with what we reported at the time of our top line data readout as well as the Phase 2a portion of the trial. Of note, there was a Grade 2 upper respiratory infection reported in both the Descartes-08 and placebo groups. There were no other new AEs reported after Month 3 follow-up, including no hypogammaglobulinemia and other infections and there was no difference in vaccine titers between Descartes-08 and placebo.

The table below summarizes the safety results observed.

	Descartes-08 (n=20)			Placebo (n=16)		
	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
Headache	7 (35%)	4 (20%)		2 (13%)	3 (19%)	
Chills	8 (40%)	4 (20%)				
Nausea	3 (15%)	6 (30%)		1 (6%)	2 (13%)	
Fever	7 (35%)	4 (20%)	1 (5%)			
Fatigue	4 (20%)	1 (5%)		1 (6%)		
Myalgia	4 (20%)	2 (10%)				
Infusion related reaction	1 (5%)	2 (10%)	1 (5%)	1 (6%)		
Muscle weakness	1 (5%)	1 (5%)		1 (6%)		
Arthralgia	1 (5%)	1 (5%)			1 (6%)	
Tachycardia	3 (15%)					
Upper respiratory infection		1 (5%)			1 (6%)	
Herpes simplex reactivation	1 (5%)		1 (5%)			
Dysgeusia	3 (15%)					
Diarrhea	1 (5%)				1 (6%)	
Sweating	1 (5%)			1 (6%)		
Limb edema	1 (5%)	1 (5%)				
Flushing	2 (10%)					
Dyspnea	1 (5%)	1 (5%)				
Insomnia	2 (10%)					
Vomiting	2 (10%)	1 (5%)				
Tremor	2 (10%)					

- **Most commonly observed AEs through Month 3 include: headache, chills, nausea and fever, all of which typically resolved within 24 hours of infusion**
- **No AEs reported after Month 3**
- **No hypogammaglobulinemia or increased infections reported**
- **No difference in vaccine titers between Descartes-08 and placebo**

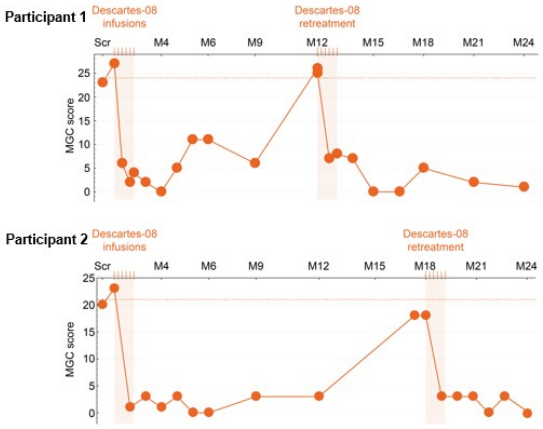
Total AEs reported through Month 12 for Descartes-08-treated patients and through Month 3 for placebo-treated patients

Safety dataset comprises all subjects who received at least one dose of Descartes-08 (n=20) or placebo (n=16)

All Grade 1–2 adverse events deemed possibly, probably or definitely related to the study drug with a cumulative incidence ≥10% and all Grade 3 adverse events deemed possibly, probably or definitely related to the study drug are reported. There were no Grade 4 adverse events

We previously reported that there were three participants in the Phase 2a portion of the trial who were observed to have a response to Descartes-08, but then reverted to baseline, two patients one year after treatment and the other 1.5 years after treatment. As previously reported, there were two participants who were retreated and experienced rapid improvements in clinical scores and maintained minimum symptom expression for up to one year after receiving a second treatment cycle.

The tables below set forth key findings from these patients.



- Three participants retreated to date, two of whom maintain minimum symptom expression 2 years after initial treatment
- Third participant's response deepened from a 4-point MG-ADL reduction at Month 2 to a 9-point improvement in MG-ADL at Month 12 following retreatment

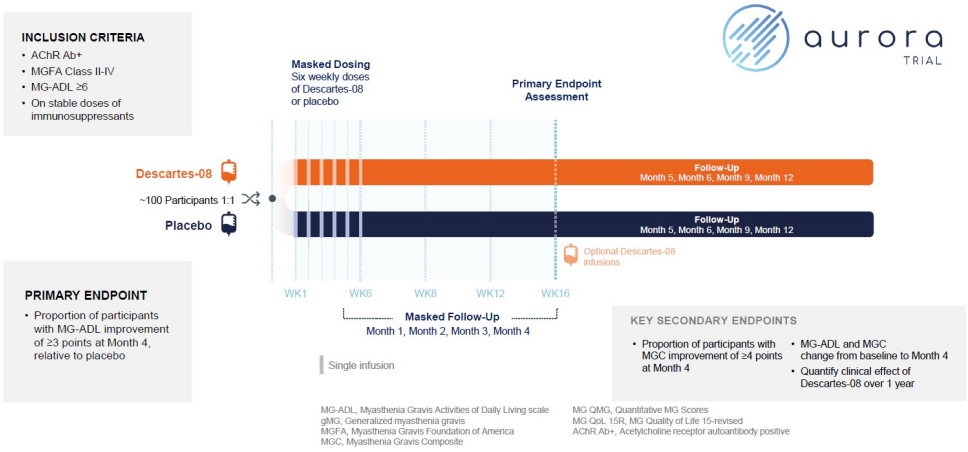
Nature Medicine publication can be found here

The time course and magnitude of treatment response upon retreatment were similar to those seen when the participants were first treated. Notably, in the one participant who completed their 12-month retreatment follow-up visit, the duration of response was observed to be longer than that patient's initial response, and this patient had maintained minimum symptom expression at Month 12. The third retreated participant's responses deepened from a 4-point MG-ADL reduction at Month 2 to a 9-point improvement in MG-ADL at Month 12 following retreatment.

In May 2025, we initiated our Phase 3 AURORA trial of Descartes-08 in patients with MG. The randomized, double-blind, placebo-controlled Phase 3 AURORA trial is designed to assess Descartes-08 versus placebo (1:1 randomization) administered as six weekly outpatient infusions without preconditioning chemotherapy in approximately 100 participants with AChR Ab+, MG. The primary endpoint will assess the proportion of Descartes-08 participants with an improvement in MG-ADL score of

three points or more at Month 4 compared to placebo. Secondary endpoints will assess safety and tolerability and the proportion of participants with a reduction of four points or more in MG Composite, or MGC, score, as well as improvements in other validated MG severity scales, including QMG, and MG Quality of Life Revised Scale, or MG-QoL-15R. In January 2025, we received written agreement from the FDA under the Special Protocol Assessment, or SPA, process on the overall design of our planned AURORA trial. The SPA agreement indicates that the FDA has determined that the proposed trial design is acceptable to support a future Biologics License Application, or BLA, for Descartes-08 in MG, subject to the ultimate outcome of the trial.

The complete trial design for AURORA is set forth below.



Descartes-08 for the Treatment of Myositis

Background Information About Myositis

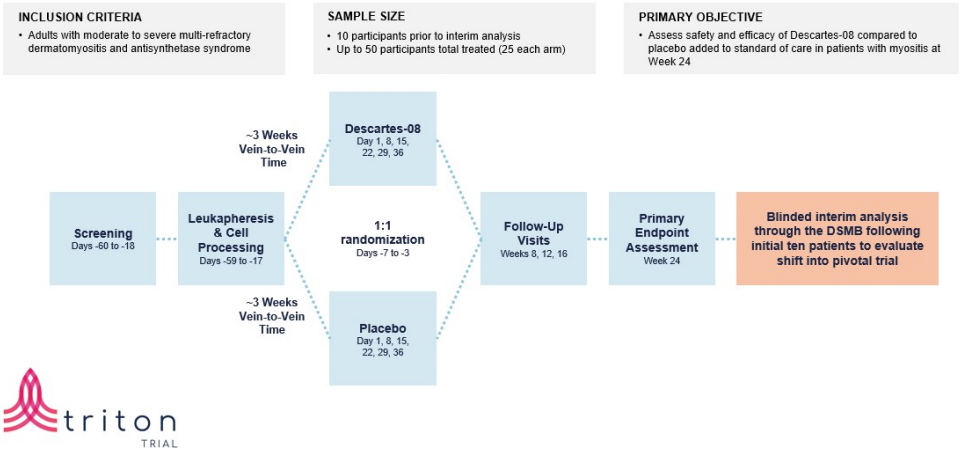
Myositis is a rare set of pathogenic autoantibody-driven diseases characterized by inflammation and muscle weakness. Myositis symptoms can range from mild to life-threatening and symptoms often include muscle weakness, joint or muscle pain, fatigue, swelling, trouble breathing or swallowing, and arrhythmia. Myositis impacts approximately 80,000 people in the United States.

Next Steps

Based on strong mechanistic alignment with our existing clinical data in MG and SLE as well as the significant unmet need that remains, in November 2025 we announced the expansion of our development of Descartes-08 into myositis, specifically dermatomyositis and antisynthetase syndrome, a significantly underserved market with high unmet need. The FDA accepted our investigational new drug application, or IND, in December 2025 for a clinical trial design which provides a potential opportunity for a single pivotal trial. We expect to commence this trial in the first half of 2026.

Our randomized, double-blind, placebo-controlled Phase 2 trial in myositis is designed to assess Descartes-08 versus placebo (1:1 randomization) administered as six weekly outpatient infusions without preconditioning chemotherapy in up to 50 patients with moderate to severe multi-refractory dermatomyositis and antisynthetase syndrome. The primary endpoint is expected to assess safety and efficacy of Descartes-08 compared to placebo added to standard of care in participants with myositis at Week 24. We currently intend to conduct a blinded interim analysis through the Data Safety Monitoring Board, or DSMB, after ten patients are enrolled and reach the primary endpoint, at which point we may revise sample size assumptions to what could be necessary to support the trial becoming pivotal, pending FDA review.

The complete trial design for this trial is set forth below.



Descartes-08 for the Treatment of Juvenile Dermatomyositis

Background Information About Juvenile Dermatomyositis

Juvenile Dermatomyositis is a rare pediatric autoimmune disorder marked by pathognomonic skin rash and muscle inflammation affecting multiple organ systems including the joints, heart, lungs, kidneys, eyes, and gastrointestinal systems. The symptoms of JDM can range from mild to life-threatening and symptoms often include fatigue, joint pain, muscle weakness and fever. JDM impacts approximately 4,000 people in the United States.

Clinical Development

In December 2024, we filed an amendment to the IND for a pediatric basket trial including juvenile dermatomyositis, or JDM. The initiation of the Phase 2 pediatric basket trial was announced in January 2026. The FDA has also granted Descartes-08 Rare Pediatric Disease Designation for the treatment of JDM. The FDA grants Rare Pediatric Disease Designation for serious and life-threatening diseases that primarily affect children ages 18 years or younger and fewer than 200,000 people in the United States. Under the FDA's recently renewed Rare Pediatric Disease Designation and priority review voucher programs, if Descartes-08 is approved for marketing in JDM, Cartesian may qualify for a priority review voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product candidate.

Descartes-08 for the Treatment of Systemic Lupus Erythematosus

Overview

In November 2025, we announced topline data from our Phase 2 trial in SLE, a chronic autoimmune disease that causes systemic inflammation which affects multiple organ systems. We also announced a pause in further development of Descartes-08 in SLE, including further enrollment in the Phase 2 trial, in order to prioritize opportunities in MG and myositis. Shortly thereafter we made a further decision to no longer pursue development of Descartes-08 in SLE. The Phase 2 trial in SLE remains ongoing for follow-up only.

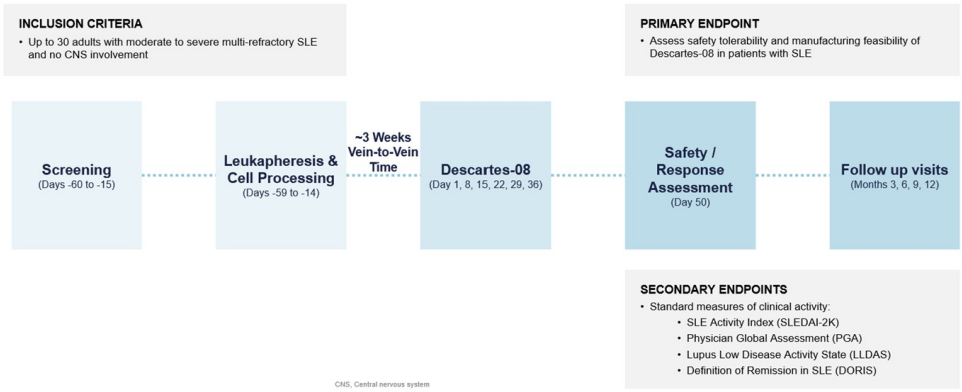
Background Information About Systemic Lupus Erythematosus

SLE is a chronic, immune-mediated connective tissue disease that can impact nearly all major organ systems. The most common manifestations of SLE are cutaneous and musculoskeletal symptoms, although neurological, gastrointestinal, hematological, and renal symptoms are regularly observed as well. Patients with SLE are at a substantially increased risk of infection and cardiovascular disease, contributing to estimated 10- and 15-year mortality rates of 9% and 15%, respectively. SLE is the most common form of lupus, representing approximately 70% of lupus patients, and approximately three million adults worldwide are estimated to have SLE.

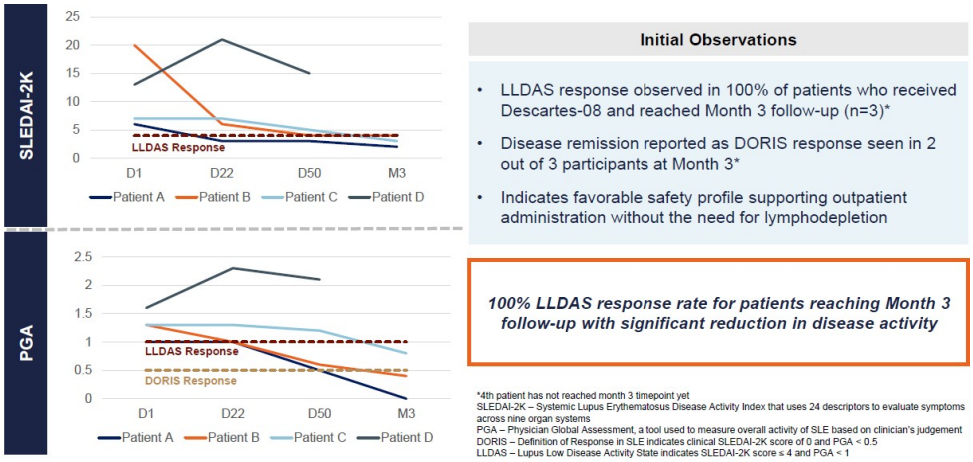
Clinical Development

The Phase 2 open-label trial was designed to evaluate outpatient administration of Descartes-08 without preconditioning chemotherapy or integrating vectors for the treatment of patients with moderate or severe SLE refractory to immunosuppressant therapy. The primary outcome measure assesses safety and tolerability, with secondary outcome measures assessing preliminary efficacy.

The complete trial design is set forth below.



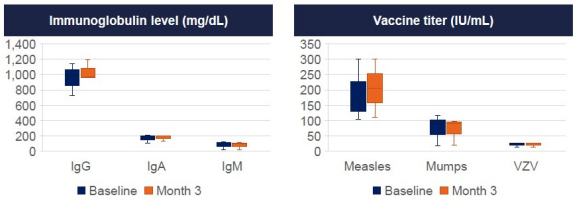
The tables below set forth the results of the Phase 2 trial.



Initial data from the Phase 2 trial reported significant reduction in disease activity following initial Descartes-08 treatment with 100% of participants who reached Month 3 follow-up (n=3) achieving Lupus Low Disease Activity State, or LLDAS, response, defined by specific criteria that indicate low disease activity, improved patient outcomes, and sustained symptom improvement. Disease remission reported as DORIS response was seen in 2 out of 3 participants at Month 3. DORIS is defined as the Definition of Response in SLE indicating a clinical SLE Disease Activity Index, or SLEDAI-2K score of 0 and physician global assessment, or PGA, of less than 0.5. We believe these results suggest that Descartes-08 may have clinical effect in the field of autoimmune disease broadly.

The tables below set forth the safety results from the Phase 2 trial.

	Grade 1	Grade 2
Fever	3 (75%)	1 (25%)
Headache	1 (25%)	1 (25%)
Chills	1 (25%)	1 (25%)
Fatigue	1 (25%)	1 (25%)
Myalgia	1 (25%)	1 (25%)
Nausea	2 (50%)	
Nasal congestion	1 (25%)	
Lightheadedness	1 (25%)	
Arthralgia	1 (25%)	



- **Infusion-related fever and flu-like symptoms were the most common AE, and all resolved within 24 hours**
- **No new safety signals identified**
- **No Grade ≥3 or serious adverse events reported to date**
- **No hypogammaglobulinemia or decrease in vaccine titers observed**

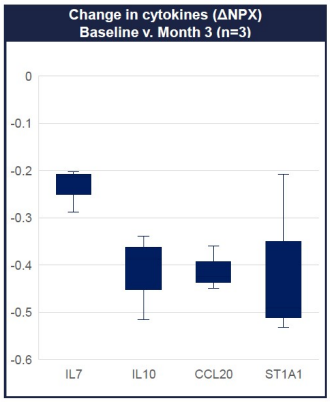
Safety dataset comprises all subjects who received at least one dose of Descartes-08 (n=4)

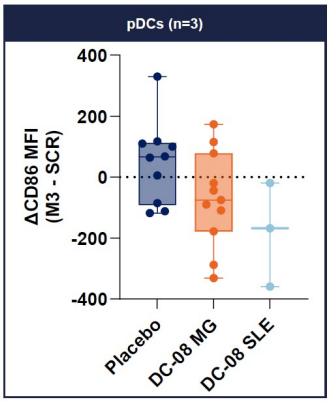
All Grade 1–2 adverse events deemed possibly, probably or definitely related to the study drug are reported. There were no Grade 3 or Grade 4 adverse events.

AE: adverse event, Ig: Immunoglobulin, VZV: Varicella zoster virus

In this trial, Descartes-08 continued to be observed as well-tolerated, supporting outpatient administration without the need for lymphodepleting chemotherapy. AEs reported were transient and mostly mild, with no AEs above Grade 2 or SAEs and notably, there were no cases of CRS and no cases of immune effector cell-associated neurotoxicity syndrome. Infusion-related fever and flu-like symptoms were the most common AEs, and all resolved within 24 hours. No hypogammaglobulinemia or decrease in vaccine titers were observed and immunoglobulin levels were consistent with measurements at baseline.

We believe observations of correlative biomarkers support application of Descartes-08 in multiple autoimmune diseases. In particular, we observed a statistically significant ($p<0.01$) decrease in proinflammatory cytokines associated with SLE pathogenesis (IL7, IL10, CCL20, ST1A1). Additionally, significant decreases were observed in plasmacytoid dendritic cells, or pDCs, three months after receiving Descartes-08 in both MG and SLE patients, which we believe supports the expansion into myositis, given myositis' known pDC correlation.





- Observed statistically significant ($p<0.01$) decrease in proinflammatory cytokines associated with SLE pathogenesis (IL7, IL10, CCL20, ST1A1) associated with disease severity in myositis, systemic sclerosis, Sjögren's syndrome and other autoimmune diseases
- Significant decrease in plasmacytoid dendritic cells (pDCs) observed 3 months after Descartes-08 in both MG and SLE patients supports the expansion into myositis, an autoimmune indication with known pDC involvement

Meitei et al. Autoimmun Rev 2021, Zeng et al. Front Immunol 2025, Bai et al. Clin Rheumatol 2021, Lisi et al. Lab Invest 2012, Nguyen et al. Arthritis Rheumatol 2025,

Descartes-15

Descartes-15 is a next-generation, autologous anti-BCMA mRNA CAR-T. Using our proprietary technology and manufacturing platform, we designed Descartes-15 to be more resistant than Descartes-08 to recycling of the CAR upon multiple antigen exposures. We observed that Descartes-15 was 10-fold more potent than Descartes-08 in preclinical studies. In November 2025, we reported results from the Phase 1 dose escalation trial designed to assess safety and tolerability of outpatient administration of Descartes-15 in patients with multiple myeloma. In this trial, no significant AEs or dose-limiting

toxicities were reported in any of the three participants. The only Descartes-15-related adverse event was a grade 2 hypotension occurring after the first two infusions. Despite favorable safety data observed in this trial, we have paused further development of Descartes-15 to prioritize opportunities for Descartes-08 in MG and myositis.

In-Vivo Development

Our current pipeline consists of autologous treatments for patients. However, there have been recent advancements within the in-vivo space. An in-vivo cell therapy treats disease by modifying a patient's cells inside their body, rather than doing so via autologous means. In-vivo treatment options create an opportunity for more convenient dosing with less frequent procedures. As we advance our pipeline, we continue to evaluate the potential of enhanced delivery platforms for our cell therapies with multiple feasibility studies underway to explore the potential timing for optimizing in-vivo delivery of our assets currently in development.

Manufacturing

We have established wholly-owned internal manufacturing and research and development capabilities, designed to allow us to optimize processes rapidly in an iterative manner and maintain control over the critical components of the supply chain. Our main manufacturing facility is located in Frederick, Maryland, and operates under current good manufacturing practice, or cGMP. This facility has sufficient capacity to support current clinical needs and can potentially transition to support commercial manufacturing of our maturing pipeline of innovative cell therapies for the treatment of autoimmune diseases. We believe the Frederick facility has the potential to allow us to scale our wholly-owned, in-house cGMP manufacturing capabilities for late-stage clinical and commercial supply of our cell therapy product candidates, while continuing to maintain control over product quality and production.

We manufacture Descartes-08 in-house and are typically able to process and release lots for infusion within approximately three weeks. Our autologous cell therapy product candidates, including Descartes-08, are manufactured on a patient-by-patient basis. We have optimized our manufacturing processes through over 200 cGMP runs across all of our current and prior programs.

Intellectual Property

Our success depends in part on our ability to obtain, maintain, protect, defend and enforce proprietary rights for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others, and in part on our ability to prevent others from infringing, misappropriating or violating our proprietary rights. A discussion of risks relating to intellectual property is provided under the section titled "Risk Factors—Risks Related to Our Intellectual Property."

We intend to continue developing intellectual property, and we intend to aggressively protect our position in key technologies. Our patents are focused on several key technologies, including the use of our mRNA CAR-T technology and other developments in our mRNA cell therapy pipeline. As of December 31, 2025, we had seven issued patents worldwide, including three patents issued in the United States (U.S. Patent Nos. 10,934,337, 11,220,535, and 11,999,773) and four patents issued outside the United States (Japanese Patent No. 7,379,654, Canadian Patent No. 3,158,025, Israeli Patent No. 285909, and Korean Patent No. 102588292). Our issued patents and any patents issuing from our pending applications are set to expire on various dates ranging from 2040 to 2044. Additionally, as of December 31, 2025, we had 24 patent applications pending worldwide, including seven U.S. applications and seventeen applications in ex-U.S. jurisdictions. A patent granted from U.S. Patent Application No. 18/654,279 will expire on March 13, 2040, a patent granted from U.S. Patent Application No. 17/919,092 will expire on April 15, 2041, a patent granted from U.S. Patent Application No. 18/292,670 will expire on July 28, 2042, a patent granted from U.S. Patent Application No. 19/166,014 will expire on March 15, 2044, and a patent granted from U.S. Patent Application No. 19/166,759 will expire on March 20, 2044, excluding any potential patent term adjustments, patent term extensions, or terminal disclaimers. These U.S. patent applications are directed to compositions of matter, methods of use, and methods of manufacture. In addition, a patent granted on any of foreign patent applications EP 20773688.5, AU 2020241428, CA 3199205, CN 202080020956.1, IN 202117036675, KR 2023-7034215, and MX/a/2021/011196 will expire March 2040, a patent granted on European patent application 21789568.9 will expire April 2041, and a patent granted on any of foreign patent application EP 24775468.2, AU 2024240255, BR112025019788-6, CA 3286127, CN 202480031788.4, JP 2025-554182, KR 10-2025-7034765, MX/a/2025/010878, and SG 11202506142T will expire March 2044. All of these patent applications are composition-of-matter, methods-of-use, and/or methods-of-manufacture applications. There are also two pending U.S. provisional applications, and any patent ultimately claiming priority to one of these provisional applications will expire in or around 2046. In addition, as of December 31, 2025, we had two registered marks protecting our brand and prospective products both domestically and internationally. With respect to the legacy Selecta assets, as of December 31, 2025, we had (i) 294 issued patents worldwide, including 14 patents issued in the United States and 280 issued outside the United

States, set to expire on various dates in 2032 through 2040, (ii) 75 patent applications pending worldwide, including 13 U.S. applications and 62 applications outside the United States and (iii) two registered marks.

In addition to patent protection, we also rely on trade secrets, know-how, trademarks, confidential information, other proprietary information and continuing technological innovation to develop, strengthen and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, consultants, contractors and collaborators, third-parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality and invention assignment agreements upon the commencement of employment or consulting relationships with us. However, such confidentiality agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see the section titled "Risk factors—Risks Related to Our Intellectual Property."

Key Agreements

Biogen License Agreement

On September 8, 2023, we entered into a non-exclusive, sublicensable, worldwide, perpetual license agreement, or the Biogen Agreement, with Biogen MA, Inc., or Biogen, to research, develop, make, use, offer, sell and import products or processes containing or using an engineering T-cell modified with an mRNA comprising, or encoding a protein comprising, certain sequences licensed under the Biogen Agreement for the prevention, treatment, palliation and management of autoimmune diseases and disorders, excluding cancers, neoplastic disorders, and paraneoplastic disorders. We are not obligated to pay Biogen any expenses, fees, or royalties.

We may terminate the Biogen Agreement for any reason or no reason, and Biogen may terminate the agreement after a notice-and-cure period of 30 days if we fail to pay a fee owed to Biogen or for any other material breach of the agreement. The Biogen Agreement will otherwise expire when all claims of all issued patents within the patents and patent applications licensed to us under the Biogen Agreement have expired or been finally rendered revoked, invalid or unenforceable by a decision of a court or government agency.

The Biogen Agreement encompasses patents and patent applications in the PCT/US2010/026825 patent family, which was filed March 10, 2010. In general, all patents that issue in this family have an expected expiration date of March 10, 2030, subject to potential patent term adjustments and/or extensions. For the U.S. patents and applications in this family, U.S. Patent 9,034,324 was awarded 677 days of patent term adjustment, which would extend the expiration date of this patent to January 16, 2032, absent any challenges to the patent term. The other issued patent in this family was not awarded any patent term adjustment, so its expected expiration date is March 10, 2030.

NCI License Agreement

Effective September 16, 2019, we entered into a non-exclusive, worldwide license agreement, or the NCI Agreement, with the U.S. Department of Health and Human Services, represented by the National Cancer Institute of the National Institutes of Health, or NCI.

Under the NCI Agreement, we were granted a license under certain NCI patents and patent applications designated in the agreement, to make, use, sell, offer and import products and processes within the scope of the patents and applications licensed under the NCI Agreement when developing and manufacturing anti-BCMA CAR-T cell products for the treatment of MG, pemphigus vulgaris, and immune thrombocytopenic purpura according to methods designated in the NCI Agreement.

In connection with our entry into the NCI Agreement, we paid to NCI a one-time $100,000 license royalty payment. Under the NCI Agreement, we are further required to pay NCI a low five-digit annual royalty. We must also pay earned royalties on net sales in a low single-digit percentage and pay up to $0.8 million in benchmark royalties upon our achievement of designated benchmarks that are based on the commercial development plan agreed between the parties.

Under the NCI Agreement, we must use reasonable commercial efforts to bring licensed products and licensed processes to the point of Practical Application (as defined in the NCI Agreement). Upon our first commercial sale, we must use reasonable commercial efforts to make licensed products and licensed processes reasonably accessible to the United States public. After our first commercial sale, we must make reasonable quantities of licensed products or materials produced via licensed processes available to patient assistance programs and develop educational materials detailing the licensed products. Unless we obtain a waiver from NCI, we must have licensed products and licensed processes manufactured substantially in the United States. Prior

to the first commercial sale, upon NCI's request, we are obligated to provide NCI with commercially reasonable quantities of licensed products made through licensed processes to be used for in vitro research.

Additionally, we must use reasonable commercial efforts to initiate a Phase 3 clinical trial of a licensed product by the fourth quarter of 2024, submit a BLA with respect to a licensed product by the fourth quarter of 2026, and make a first commercial sale of a licensed product by the fourth quarter of 2028.

The NCI Agreement terminates upon the expiration of the last to expire of the patent rights licensed thereunder, if not sooner terminated. The NCI License Agreement encompasses patents and patent applications in the PCT/US2013/032029 patent family, which was filed March 15, 2013. In general, all patents that issue in this family have an expected expiration of March 15, 2033, subject to potential patent term adjustments and/or extensions. For the U.S. patents and applications in this family, only two patents were awarded patent term adjustments. U.S. Patent 9,765,342 was awarded 297 days of patent term adjustment, which would extend the expiration date of this patent to January 6, 2034, absent any challenges to the patent term. The other patent, U.S. Patent 10,876,123, was awarded three days of patent term adjustment, but this patent is subject to terminal disclaimers filed against other family members, so this patent will not extend beyond the March 15, 2033 date. The other issued patents in this family were not awarded any patent term adjustment, so the expected expiration date for these patents also remains March 15, 2033. There is also a pending patent application which, if issued, will expire on March 15, 2033, but could also be subject to patent term adjustment and to any potential future terminal disclaimers. NCI has the right to terminate this agreement, after giving written notice and providing a cure period in accordance with its terms, if we are in default of a material obligation. We have the unilateral right to terminate the agreement in any country or territory by giving NCI 60 days' written notice. We agreed to indemnify NCI against any liability arising out of our, sublicensees' or third-parties' use of the licensed patent rights and licensed products or licensed processes developed in connection with the licensed patent rights.

Sobi License Agreement

On June 11, 2020, we entered into a License and Development Agreement with Swedish Orphan Biovitrum AB (publ.), or Sobi, which was amended on October 31, 2023, or, as so amended, the Sobi License. Pursuant to the Sobi License, we granted Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize a drug candidate Nanoecapsulated Sirolimus plus Pegadricase, or NASP, formerly known as SEL-212, which is currently in development for the treatment of chronic refractory gout. Pursuant to the Sobi License, Sobi agreed to make milestone payments totaling up to $630.0 million to us upon the achievement of various development and regulatory milestones and, if commercialized, sales thresholds for annual net sales of NASP, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier. Any proceeds received from milestone payments or royalties relating to the Sobi License would be required to be distributed to holders of CVRs, net of certain deductions.

The transactions contemplated by the Sobi License were consummated on July 28, 2020. Sobi may terminate the Sobi License for any reason upon 180 days' written notice, whereby all rights granted under the Sobi License would revert back to us. In addition, if Sobi were to terminate the Sobi License, we have the option to obtain a license to all patents and know-how necessary to exploit NASP in existence as of the termination date from Sobi in return for making an equitable royalty payment to Sobi.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future. Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing 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. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of any other cell therapy product candidates that we develop, if approved, are likely to be their efficacy, durability of response, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we

may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products.

Descartes-08 may compete with products of other companies in the MG market, including Amgen, Argenx SE, UCB S.A., Johnson & Johnson through its Janssen Pharmaceuticals, Inc. subsidiary, AstraZeneca PLC through its Alexion Pharmaceuticals, Inc. subsidiary, Kyverna Therapeutics, Inc. and Cabaletta Bio, Inc.

Other companies developing CAR-T therapies include large, fully integrated pharmaceutical companies such as Novartis AG, Gilead Sciences, Inc., through its Kite Pharma, Inc. subsidiary, Bristol-Myers Squibb Company, and biopharmaceutical companies such as Kyverna Therapeutics, Inc. and Cabaletta Bio, Inc.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing.

We believe our cell therapy product candidates are subject to regulation in the United States as “biologics” or “biological products.” We expect to seek approval of Descartes-08 through a BLA reviewed by FDA’s Center for Biologics Evaluation and Research, or CBER.

Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or the FD&C Act, and the Public Health Service Act, or the PHS Act, and other federal, state, local and foreign statutes and regulations. Descartes-08 and any other product candidates that we develop must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries.

We regard our mRNA-modified products as cell therapy products and not as genetic engineering or gene therapy products, because mRNA modifications are not embodied in DNA or incorporated into a genome. However, it is possible that in some jurisdictions, regulations on genetic engineering or genetic therapy may intentionally or unintentionally apply to our technology. This could create additional regulatory burden.

U.S. Biological Products Development Process

The process required by the FDA before a biologic, including a cell therapy, may be marketed in the United States is summarized below.

Biological product candidates are preclinically tested before any testing is done in humans. These tests, or non-clinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal requirements including good laboratory practices, or GLPs.

The clinical study sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND which must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns, non-compliance with regulatory requirements, or other issues. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. In addition to these requirements, biological product candidates may also require evaluation and assessment by an institutional biosafety committee, or IBC, that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at an institution participating in a clinical trial.

Clinical trials are conducted under protocols detailing the objectives of the clinical study, dosing procedures, patient selection and exclusion criteria, and the parameters to be used to monitor patient safety. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA’s regulations, including with respect to good clinical practice, or GCP, requirements, including the requirement that all research subjects provide informed consent. Further, each clinical study must be reviewed and approved by an institutional review board, or IRB, at or servicing each institution at which the clinical study will be conducted. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological product candidate is evaluated in a limited population of patients or healthy volunteers to identify the maximum tolerated dose, recommended Phase 2 dose, possible adverse effects and safety risks. For the types of products and therapeutic areas we focus on, Phase 1 studies will generally be done in patients and not healthy volunteers.
- Phase 2. The biological product candidate is evaluated in a broader population to evaluate safety further and preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine the optimal dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical study 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.

Cell and gene therapy products may differ from the traditional clinical trial phases. For example, clinical trials for cell and gene therapy products are often structured as a hybrid Phase 1/2 trial where a small group of participants with the disease are enrolled and both safety and efficacy tests are performed.

Through the SPA process, a sponsor may seek agreement from the FDA on critical features of a proposed protocol for their adequacy to support marketing approval. In response to a request for an SPA agreement, the FDA issues a letter to the sponsor indicating its agreement or non-agreement with elements of the proposed protocol. An SPA agreement documents the FDA's concurrence with the adequacy and acceptability of specific critical elements of the protocol design, and the FDA may not change an SPA agreement once the trial is underway unless the sponsor or applicant agrees in writing or the FDA identifies a substantial scientific issue essential to determining the safety or effectiveness of the drug after the testing has begun. Even if the sponsor conducts the trial in accordance with an SPA agreement and the trial meets its endpoints with statistical significance, there is no guarantee that the FDA will accept or approve a marketing application. For example, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support approval, or only justifies approval for a narrow set of clinical uses or approval with restricted distribution or other post-approval requirements or limitations. In January 2025, we received written agreement under the SPA process on overall design of the our planned Phase 3 AURORA trial for Descartes-08 in MG. The SPA agreement indicates that the FDA has determined that the proposed trial design is acceptable to support a future BLA for Descartes-08 in MG, subject to the ultimate outcome of the trial.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

The FDA or the sponsor or a separate data safety monitoring board may suspend or terminate a clinical study at any time on various grounds. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients or otherwise in the interest of patient welfare.

Sponsors of clinical trials of FDA-regulated products, including biologics, are also required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

After the completion of clinical trials of a biological product candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain a pediatric assessment unless the applicant has obtained a waiver or deferral. Pediatric assessment contains data gathered from pediatric studies using appropriate formulations for each age group for which the assessment is required and other data adequate to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors with an application for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must submit an initial Pediatric Study Plan, or PSP, (or a deferral or waiver, as appropriate) within 60 days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Under the Prescription Drug Fee User Act, as amended, or PDUFA, each BLA must be accompanied by a substantial user fee. Fee waiver or reductions are available under certain circumstances, including for the first application filed by a small business. In addition, no user fees are assessed on BLAs on products designated as orphan drugs unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA conducts a preliminary review of a BLA to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information before deciding whether to accept a BLA for filing. The FDA may refuse to file any BLA that it deems incomplete or otherwise not reviewable and may request additional information. If the submission is accepted for filing, the FDA substantively reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, and manufactured in accordance with appropriate procedures and controls to ensure product quality. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a non-binding recommendation on approval. The FDA may waive the review by an advisory committee and is not bound by the recommendation of an advisory committee, but it often follows such recommendations. During the biological product approval process, the FDA also will review proposed product labeling and will determine whether a Risk Evaluation and Mitigate Strategy, or REMS, is necessary to assure the safe use of the biological product candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities in which the product is manufactured to determine whether the manufacturing processes and facilities are in compliance with cGMPs. The FDA may also audit the clinical investigation sites to determine that they have complied with GCPs.

Notwithstanding the submission of relevant data and information, the FDA may ultimately deny approval or seek additional information from the applicant. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the applicant interprets the same data. The FDA may also raise questions about product manufacturing and quality control. If the FDA denies approval of a BLA in its then-current form, the FDA will issue a complete response letter detailing deficiencies in the application. If a response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

One of the performance goals agreed to by the FDA under PDUFA is to review 90% of standard BLAs in 10 months from the filing date and 90% of priority BLAs in six months from the filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs.

Orphan Designation

Prior to the submission of a BLA, the FDA may grant orphan designation to drugs or biologics intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and marketing the product for this type of disease or condition will be recovered from sales in the United States. 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.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other application to market the "same drug" for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. The scope of any eventual orphan exclusivity relative to the orphan designation is the subject of ongoing litigation and as such is uncertain and may change. For example, under FDA regulations, a designated orphan product may not receive orphan exclusivity for a use that is broader than the indication for which it received orphan designation and FDA approval. However, in 2021, the U.S. Court of Appeals for the Eleventh Circuit in Catalyst Pharmaceuticals, Inc. v. Becerra adopted a broader interpretation of the scope of orphan exclusivity. The court in Catalyst held that orphan exclusivity blocks approval of another company's application for the "same drug" for the "entire disease or condition" for which the drug is granted orphan designation, regardless of whether the product was approved only for a narrower use or indication. Similarly, in 2025, the U.S. District Court for the District of Columbia in Neurelis v. Brenner adopted the same reasoning as the court in Catalyst to reach the same conclusion. Although the FDA announced in January 2023 that it will not apply the Catalyst decision beyond the facts at issue in that case, neither a court of appeals nor FDA has addressed Neurelis and either Catalyst or Neurelis could serve as a precedent for future challenges to the FDA's orphan product-related decisions.

Orphan exclusivity may be lost if the FDA later determines that the orphan designation request was materially defective or if the manufacturer is unable to ensure the availability of sufficient quantities of the drug to meet the needs of patients with the rare disease or condition, or if the manufacturer chooses to provide consent to FDA approval of other applications.

Descartes-08 has been granted Orphan Drug Designation for the treatment of MG.

Expedited Development and Review Programs

The FDA offers various programs, including the Fast Track program, Breakthrough Therapy designation, RMAT designation and the National Priority Voucher, or CNPV, program that are intended to expedite or facilitate the process for reviewing new biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a Fast Track product at any time during the clinical development of the product.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of treatment, diagnosis, or prevention compared to available therapies.

Additionally, a product may be eligible for accelerated approval. The FDA may approve a product for a serious or life-threatening disease or condition based on a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product subject to accelerated approval perform adequate and well-controlled post-marketing clinical studies to confirm such benefit. The Food and Drug Omnibus Reform Act of 2022, or FDORA, added the failure to conduct post-approval studies with due diligence or to submit timely progress reports on such studies to the list of prohibited acts under the FD&C Act, which means that any such failures, whether they result from a sponsor's actions or the actions of third-parties, could provide the basis for withdrawal of the product on an expedited basis or other enforcement actions. In addition, the FDA currently requires as a condition for accelerated approval that promotional materials be submitted prior to use, which could adversely impact the timing of the commercial launch of the product.

In addition, under the provisions of The Food and Drug Safety and Innovation Act, or FDASIA, Congress and the FDA established a Breakthrough Therapy Designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases or conditions. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over 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 features of Fast Track designation, as well as more intensive FDA interaction and guidance. Fast Track, priority review, accelerated approval, and breakthrough therapy designations do not change the standards for approval and may not necessarily expedite the development or approval process.

In 2016, the 21st Century Cures Act established what the FDA describes as RMAT designation. The RMAT designation program is intended to facilitate an efficient development program for, and expedite review of, any product that meets the following criteria: (i) the product qualifies as an RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the product is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of Breakthrough Therapy Designation, including early interactions to discuss any potential surrogate or intermediate endpoints to be used to support accelerated approval, eligibility for rolling review and potential eligibility for priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites, as appropriate.

Descartes-08 has been granted RMAT designation for the treatment of MG.

In 2025, the FDA also announced the opportunity for prescription drug and biological product companies to participate in the FDA Commissioner's CNPV pilot program. Companies selected for the CNPV program will be issued a voucher entitling

the company to benefits including enhanced communications and rolling review to allow for a shortened review time. CNPV does not change the standards for approval and may not necessarily expedite the development or approval process.

Post-approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products include record-keeping requirements, reporting of adverse effects and reporting updated safety and efficacy information.

We also must comply with the FDA's advertising and promotion requirements, such as the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling, known as "off-label use," and the requirement to balance information provided about a product's benefits with important safety information. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions, expensive and onerous government investigations, and adverse publicity.

Conventional DNA-modified CAR-T cell products have been subject to extensive post-approval surveillance requirements. Because the mRNA of our products is temporary, we do not believe that our mRNA-modified products will be subject to requirements of this nature, although other post-approval requirements will apply.

Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, or ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or 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. The FDA has approved a number of products under these provisions.

To our knowledge, how the definition of "biosimilar" applies with regard to an mRNA-modified cell therapy has not been expressly stated in statute, regulation, or guidance, and has not been reviewed by a court. The regulatory pathway for a biosimilar to one of our products thus remains somewhat uncertain.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. A biological product may also obtain pediatric exclusivity in the United States. For a biological product, pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study or studies.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty. For example, the FDA had previously required comparative clinical studies to support a demonstration of biosimilarity if there is residual uncertainty about whether there are clinically meaningful differences between the reference product and the proposed product. However, in October 2025, the FDA issued a new draft guidance document that largely permits biosimilar applications without comparative efficacy studies, thus potentially increasing the risk of sooner biosimilar entry.

Government Regulation Outside of the United States

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in countries outside the United States prior to the commencement of clinical studies or marketing of the product in those countries.

The requirements and process governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical studies must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

In the European Economic Area, or EEA, which is composed of the 27 member states of the European Union, or EU, plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. To obtain an MA in the EEA, we must submit a marketing authorization application, which is similar to the U.S. BLA. There are two types of MAs.

The EU MA, which is issued by the European Commission through the Centralized Procedure, is based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy medicinal products (comprising gene therapy, somatic cell therapy and tissue engineered products), among others. The Centralized Procedure is optional for other products containing a new active substance not yet authorized in the EEA, or for other products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases. Under the accelerated procedure the standard 210 days review period is reduced to 150 days.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

EU law also provides opportunities for market exclusivity. Upon receiving MA, “new active substances” generally receive eight years of data exclusivity, which prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic or biosimilar application, and an additional two years of market exclusivity, during which no generic or biosimilar product can be marketed. The ten years of exclusivity will be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU’s regulatory authorities to be a new active substance which would be eligible for the relevant periods of data and market exclusivity.

The criteria for designating an “orphan medicinal product” in the EU are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for certain financial and exclusivity incentives. In particular, orphan medicinal products in the EU can receive ten years of market exclusivity, during which time no MA application shall be accepted, and no MA shall be granted for a similar medicinal product for the same indication. The 10-year market exclusivity for orphan medicinal products may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation. Additionally, MA may be granted to a similar product during the 10-year period of market exclusivity for the same therapeutic indication at any time in certain circumstances, including if the second applicant can establish in its application that its product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior.

In the EU, for any new medicinal product that is protected by or eligible for a supplementary protection certificate, pediatric clinical trials must be conducted in accordance with a pediatric investigation plan, or PIP, that has been approved by the EMA. Normally, the pediatric clinical trials must be completed before the initial MA application for the relevant indication. However, the EMA may grant a deferral of the studies in order not to delay the approval of the product in adults and the EMA may waive the requirement to conduct studies in certain circumstances, such as if the relevant condition does not occur in children. If pediatric clinical trials are completed in accordance with an agreed PIP, the product will be entitled to a six-month extension of its supplementary protection certificate. However, if the product is authorized as an orphan medicinal product, it is entitled to a two-year extension of its 10 years of orphan exclusivity and not to an extension of the supplementary protection certificate.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all

cases, again, the clinical studies must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

When conducting clinical trials in the EU, we must adhere to the provisions of the EU Clinical Trials Regulation (EU) No 536/2014. If the sponsor of the clinical trial is not established within the EU, it must appoint an entity within the EU to act as its legal representative, who shall be responsible for ensuring compliance with the sponsor's obligations under the Regulation and be the addressee for all communications. The sponsor must take out a clinical trial insurance policy, and in most EU countries the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial in the EU, we must obtain a clinical trial authorization, or CTA, in each Member State in which the trial will be conducted. There is a centralized application procedure where one national authority leads the scientific review of the application, while each concerned member state complete an ethical review of any CTA. The application for a CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Any substantial changes to the trial protocol or other information submitted with the CTAs must be notified to or approved by the relevant competent authorities.

We are also subject to data privacy and security laws in the jurisdictions outside of the U.S. in which we are established, run clinical trials or in which we sell or market our products once approved. For example, in Europe we are subject to Regulation (EU) 2016/679 (General Data Protection Regular, or GDPR) in relation to our collection, control, processing and other use of personal data (i.e., data relating to an identifiable living individual). We process personal data in relation to participants in our clinical trials in the EEA, including the health and medical information of these participants. The GDPR is directly applicable in each EU Member State, however, it provides that EU Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes accountability and transparency obligations regarding personal data. We are also subject to EU rules with respect to cross-border transfers of personal data out of the EU and EEA. We are subject to the supervision of local data protection authorities in those EU jurisdictions where we are established or otherwise subject to the GDPR. A breach of the GDPR could result in significant fines, regulatory investigations, reputational damage, orders to cease/ change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Other Healthcare Laws

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly (regardless of knowledge of this specific statute) and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, formulary managers, and other third-parties on the other. The majority of states also similar have anti-kickback laws, which in some cases apply to items and services reimbursed by private insurance.

The federal false claims and civil monetary penalties laws, including the civil False Claims Act, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation. A claim includes "any request or demand" for money or property presented to the U.S. government. Manufacturers can be held liable under false claims laws, even if they do not submit claims to the government, where they are found to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging or off-label promotion to customers that file claims. Violation of the federal Anti-Kickback Statute may also constitute a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the civil False Claims Act may be brought by the Department of Justice or as a qui tam action by a private individual in the name of the government. Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. 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.

In addition, the Physician Payments Sunshine Act requires applicable manufacturers to annually report certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers, as well as ownership and investment interests held by physicians and their immediate family members.

Sanctions under these federal and state fraud and abuse laws may include civil monetary penalties and criminal fines, exclusion from government healthcare programs, and imprisonment.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health act of 2009, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to, as well as imposed certain other privacy obligations on, "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a).

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological products for which we obtain regulatory approval. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Sales of any products for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication.

A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. The EU recently adopted Regulation (EU) 2021/2282 on health technology assessment, which provides a framework for Member States to cooperate on health technology assessments at the EU level. The regulation is directly applicable in all EU Member States which is in a phased period of applicability since January 12, 2025, although pricing will still be determined nationally. Moreover, at the national level, EU Member States may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member States may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other Member States allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially

in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any product. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products.

Federal, state and local governments in the U.S. have established and continue to consider policies to limit the growth of healthcare costs, including the cost of prescription drugs. Recently there has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted 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 prescription drugs.

At the federal level, for example, the Inflation Reduction Act of 2022, or IRA, was signed into law. Key provisions of the IRA include the following, among others:

- The IRA requires manufacturers to pay rebates for Medicare Part B and Part D drugs whose price increases exceed inflation.
- The IRA eliminated the so-called “donut hole” under Medicare Part D by requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees’ prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached. The IRA also significantly lowered the beneficiary maximum out-of-pocket cost under Medicare Part D.
- The IRA delays the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries
- The IRA directs the Centers for Medicare and Medicaid Services, or CMS, to engage in price-capped negotiation for certain Medicare Part B and Part D products. Specifically, the IRA’s Price Negotiation Program applies to high-expenditure single-source drugs and biologics that have been approved for at least seven or 11 years, respectively, among other negotiation selection criteria, beginning with 10 high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The negotiated prices will be capped at a statutorily determined ceiling price. There are certain statutory exemptions from the IRA’s Price Negotiation Program, such as for a drug that has only orphan drug designations and is approved only for an indication or indications within the scope of such designation. The IRA’s Price Negotiation Program is currently the subject of legal challenges.

Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties and a potential excise tax. The IRA permits the Secretary of Health and Human Services, or the HHS Secretary, to implement many of the IRA’s provisions through guidance, as opposed to regulation, for the initial years. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices pharmaceutical manufacturers can charge and reimbursement pharmaceutical manufacturers can receive for approved products, among other effects.

The Trump Administration has issued Executive Orders relating to prescription drug pricing and letters to pharmaceutical manufacturers that direct drug manufacturers to, among other things, offer most favored nation, or MFN, pricing in Medicaid, offer MFN pricing for all newly launched drugs; repatriate increased revenue from abroad to lower drug prices in the United States, and implement direct-to-consumer and direct-to-business distribution of their products at MFN pricing. The Administration has warned that manufacturers that fail to make “significant progress” toward MFN pricing will face enumerated regulatory and enforcement consequences. In September 2025, the Trump Administration began announcing deals with specific manufacturers to address its MFN goals.

In addition, other legislative changes have been proposed and adopted in the United States. These include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments, will stay in effect through 2032 unless additional Congressional action is taken.

The Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the biotechnology and pharmaceutical industries, transparency in decision making and ultimately the cost and availability of prescription drugs. Drug pricing is an active area for regulatory reform at both the federal and state levels, and additional significant changes to current drug pricing and reimbursement structures in the U.S. could be forthcoming. It remains unclear how any new legislation or regulation might affect the prices we may obtain for any of our product candidates for which regulatory approval is obtained.

Employees and Human Capital Resources

We consider human capital to be an essential driver of our business and successful strategy creation and execution. Our people, driven by our collaborative, pioneering, and patient-focused culture, propel our business forward, strengthening us for long-term success.

As of December 31, 2025, we had 75 full-time employees, 62 of whom are primarily engaged in research and development activities and 13 of whom are primarily engaged in corporate functions. 60% of our employees have at least one of a Masters, PhD, or MD degree. All employees reside and work in the United States and our employees are not represented by a labor union. We consider our employee relations to be strong and in good standing.

Our goal is to continually engage our talented and diverse workforce to drive value creation both for our business and ultimately our patient populations. We believe in a proactive approach to talent management focusing on retention of key talent, critical role successor identification, and impactful employment development. Additional priority areas intended to drive engagement include successful recruitment of diverse talent, continual promotion of professional development at all levels, introduction, and evolution of business-friendly human resources solutions, coupled with an intentional culture dialog aimed to drive a high engagement, high performance, patient centric culture.

To further drive attraction and retention of our high-quality, experienced, and diverse workforce, we invest in the physical, emotional, and financial well-being of our employees. These investments include a competitive mix of compensation and generous insurance benefits. To assist employees with the rising cost of healthcare, we pay 100% of an employee's deductible and co-insurance payments. All employees are eligible to participate in our equity compensation programs. All employees are awarded new hire equity and annual equity. Employees are also eligible to receive an annual cash bonus and to participate in a 401(k) retirement plan with an industry competitive company match.

Available Information

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public at the SEC's website at http://www.sec.gov. We make available on our website at www.cartesiantherapeutics.com, free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC. Additionally, our Code of Business Conduct and Ethics is available on our website. The hyperlink to our website is included as an inactive textual reference only, and the information on our website is not incorporated by reference in this Annual Report on Form 10-K or in any other filings we make with the SEC.

RISK FACTORS SUMMARY

Investing in our common stock involves various risks. You should carefully read and consider the matters discussed in this Annual Report under the heading "Risk Factors," which include the following risks:

- We are a development-stage company, and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed and on terms favorable to us, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- We develop our mRNA-based product candidates by leveraging our proprietary technology and our manufacturing platform, which is an unproven approach to the treatment of autoimmune disease. We are early in most of our clinical development efforts and may not be successful in our efforts to build a pipeline of product candidates and develop marketable drugs.
- Clinical drug development is inherently risky and involves a lengthy and expensive process, which is subject to a number of factors, many of which are outside of our control. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Interim, top-line and preliminary data from our clinical trials 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.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- We have recorded a material amount of goodwill and indefinite-lived intangible assets in connection with the Merger. We have, and may in the future, record impairment charges, which would adversely impact our financial position and results of operations.
- We expect to continue to grow our manufacturing capabilities and resources and we must incur significant costs to develop this expertise and/or rely on third-parties to manufacture our products.
- We rely, and expect to continue to rely, on third-parties, including CROs, to conduct our clinical trials, and those third-parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials.
- If we or our licensors are unable to adequately protect our proprietary technology, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would negatively impact our business.
- We have been in the past and may in the future be subject to stockholder litigation.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Annual Report. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to the Development of our Product Candidates

We develop our mRNA-based product candidates by leveraging our proprietary technology and our manufacturing platform, which is an unproven approach to the treatment of autoimmune disease. We may not be successful in our efforts to build a pipeline of product candidates and develop marketable drugs.

Our mRNA approach to develop product candidates for the treatment of autoimmune diseases is an unproven approach. Our most advanced product candidate, Descartes-08, is in Phase 3 clinical development. We have not demonstrated the ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial product, or arrange for a third-party to do so on our behalf, or conduct other sales and marketing activities necessary for

successful product commercialization. We may have problems identifying new product candidates and applying our technologies to other areas. Even if we are successful in identifying new product candidates, they may not be suitable for clinical development, including as a result of manufacturing difficulties, harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. The success of our product candidates will depend on several factors, including the following:

- design, initiation and completion of preclinical studies and clinical trials with positive results;
- reliance on third-parties, including but not limited to collaborators, licensees, clinical research organizations and contract manufacturing organizations;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates and not infringing or violating patents or other intellectual property of third-parties;
- manufacturability, manufacturing, logistics, and stability of our cell therapies, including autologous cell therapies;
- growing our internal cGMP manufacturing capabilities to support commercial manufacturing or making arrangements with third-party manufacturers;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients and the medical community;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of scientists and businesspeople who can develop and commercialize our product candidates and technology.

Our failure to successfully execute on of any of the foregoing for any reason would effectively prevent or delay approval of our lead and other product candidates.

Clinical drug development is inherently risky and involves a lengthy and expensive process which is subject to a number of factors, many of which are outside of our control. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Clinical development is expensive, time consuming and involves significant risk. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete manufacturing and preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Manufacturing cell therapies, particularly those modified with mRNA, is a new field.

Preclinical development is costly and inherently uncertain. Early preclinical results may not be predictive of future results, however, if our technology proves to be ineffective or unsafe as a result of, among other things, adverse side effects, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the clinical development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its outcome is inherently uncertain. A failed clinical trial can occur at any stage of testing. Moreover, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, we may not be able to complete, or may be required to deviate from the current clinical trial protocol for a variety of reasons.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development or early-stage clinical trials, and we cannot be certain that we will not

face similar setbacks. Serious adverse events, or SAEs, caused by, or other unexpected properties of, any product candidates that we may choose to develop could cause us, an institutional review board or regulatory authority to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable non-U.S. regulatory authorities. If any product candidate that we may choose to develop is associated with SAEs or other unexpected properties, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which those undesirable characteristics would be expected to be less prevalent, less severe or more tolerable from a risk-benefit perspective. Moreover, preclinical and clinical data is often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory authority approval. If we fail to produce positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be negatively impacted.

In addition, we cannot be certain as to what type and how many clinical trials the FDA will require us to conduct before we may gain regulatory approval to market any of our product candidates in the United States or other countries, if any. Prior to approving a new therapeutic product, the FDA generally requires that safety and efficacy be demonstrated in two adequate and well-controlled clinical trials. Although the FDA may provide comments regarding our development plan as part of an SPA agreement or otherwise, final determination for marketing application approval are made after a complete review of a marketing application and are based on the entirety of the data in the IND or BLA.

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

- clinical trials of our product candidates may produce unfavorable, incomplete or inconclusive results;
- we may be unable to manufacture our product candidates, which in some cases such as mRNA CAR-T, are manufactured on a patient-by-patient basis;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may place a clinical hold on existing clinical trials;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with CROs or clinical trial sites;
- we may be unable to recruit suitable patients to participate in a clinical trial, the number of patients required for clinical trials of our product candidates may be larger than we expect, enrollment in these clinical trials may be slower than we expect or participants may drop out of these clinical trials at a higher rate than we expect, or enrollment could be affected by unforeseen geopolitical conflict;
- the number of clinical trial sites required for clinical trials of our product candidates may be larger than we expect;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- investigators, regulators, data safety monitoring boards or institutional review boards may require that we or our investigators suspend or terminate clinical research, or we may decide to do so ourselves;
- investigators may deviate from the trial protocol, fail to conduct the trial in accordance with regulatory requirements or misreport study data;
- the cost of clinical trials of our product candidates may be greater than we expect or we may have insufficient resources to pursue or complete certain aspects of our clinical trial programs or to do so within the timeframe we planned;
- the supply or quality of raw materials or manufactured product candidates (whether provided by us or third-parties) or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or in a timely manner, or we may experience interruptions in supply;
- laboratories that we rely upon to perform certain quality control tests may become unavailable, or their services could be delayed;

- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we expect;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design of our clinical trials;
- regarding trials managed by our existing or any future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us; and
- geopolitical events may affect international and overseas trial sites in ways beyond our control.

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

- be delayed in obtaining marketing approval for our product candidates, if at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have a product removed from the market after obtaining marketing approval.

We could also encounter delays if a clinical trial is suspended or terminated. Authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. 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.

Our product development costs will increase if we experience delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, from time to time our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our common stock to decline and limit our ability to obtain additional financing.

We may conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or the complexity of regulatory burdens may otherwise adversely impact us.

Opening and conducting clinical trials at trial sites outside the United States may involve additional regulatory, administrative and financial burdens, including compliance with foreign and local requirements relating to regulatory submission and clinical trial practices. Although the FDA may accept data from clinical trials conducted outside the United

States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCPs and the FDA must be able to validate the data from the trial through an onsite inspection, if necessary. Generally, the patient population for any clinical trials conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. Nonetheless, there can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, 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 any applicable product candidates.

Additional risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- increased costs and heightened supply constraints associated with the acquisition of standard of care drugs and/or combination or comparator agents for which we may bear responsibility in certain jurisdictions;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations;
- more burdensome manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries;
- changes in country or regional regulatory requirements; and
- geopolitical instability or wars in regions outside of the United States where we conduct clinical trials may impact ongoing clinical trials.

We may not be able to qualify for or obtain various designations from regulators that would have the potential to expedite the review process of one or more of our product candidates and even if we do receive one or more such designations there is no guarantee that they will ultimately expedite the process, or aid in our obtaining marketing approval or provide market exclusivity.

There exist several designations that we can apply for from the FDA and other regulators that would provide us with various combinations of the potential for expedited regulatory review, certain financial incentives, aid in our obtaining marketing approval as well as the potential for post-approval exclusivity for a period of time. These designations include but are not limited to orphan drug designation, breakthrough therapy designation, accelerated approval, CNPV, fast track status and priority review for our product candidates. For example, Descartes-08 has been granted Orphan Drug Designation and RMAT Designation by the FDA for the treatment of MG. Descartes-08 received Rare Pediatric Disease Designation by the FDA for the treatment of JDM. We expect to seek one or more of these designations for our other current and future product candidates. There can be no assurance that any of our other product candidates will qualify for any of these designations. There can also be no assurance that any of our product candidates that do qualify for these designations will be granted such designations or that the FDA will not revoke a designation it grants at a later date, or that Congress will not change the law about a designation.

Further, there can be no assurance that any of our product candidates that are granted such designations, including Descartes-08, will ever benefit from such designations or that the FDA would not withdraw such designations once granted. Were we to receive a designation that promised a period of market exclusivity, such as orphan drug exclusivity, such exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. In particular, the scope of exclusivity afforded for mRNA-modified cell therapy products may not be well defined and may change. Further with respect to orphan drug status, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care.

Interim, top-line and preliminary data from our clinical trials 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 publish interim, top-line or preliminary data from our clinical 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 full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available.

Interim, top-line or preliminary data may not be representative of final data. If final data is not as positive as earlier interim, top-line or preliminary we have released, our business prospects would be significantly harmed.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. As a result, preliminary and top-line data should not be relied upon in making an investment decision in our securities.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities and could result in decreased market acceptance of any of our product candidates, if approved. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications.

In November 2023, the FDA issued a statement that it is investigating serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous CAR-T cell immunotherapies. While the FDA noted that it currently believes that the overall benefits of these products continue to outweigh their potential risks for their approved uses, the FDA stated that it is investigating the identified risk of T-cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action. Further, in January 2024, the FDA announced it would require a so-called “boxed warning” be added to the prescribing information for all six then-currently approved CAR-T therapies. A boxed warning is the strongest safety labeling the FDA may require. However, because all currently approved CAR T-cell immunotherapies are in oncology indications, there can be no assurance that FDA will reach the same risk-benefit analysis in other indications. In June 2025, the FDA eliminated the REMS for currently approved BCMA- and CD19-directed autologous chimeric antigen receptor CAR T cell immunotherapies, but maintained the boxed warning and stated that the products would continue to be subject to safety monitoring through AE reporting and any post-marketing commitments or requirements.

While we believe our mRNA-based CAR-T product candidates may have a differentiated toxicity profile than currently approved DNA-based CAR-T therapies, there can be no assurance that the FDA would not treat Descartes-08 or any of our other product candidates similar to approved DNA-based CAR-T therapies, or decide a REMS is necessary to assure safe use. The FDA’s investigation may impact the FDA’s review of product candidates that we are developing, or that we may seek to develop in the future, which may, among other things, result in additional regulatory scrutiny of our product candidates, delay the timing for receiving any regulatory approvals or impose additional post-approval requirements on any of our product candidates that receive regulatory approval.

Any drug-related side effects observed in our clinical trials could also affect patient enrollment in our clinical trials or the ability of any enrolled patients to complete such trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- regulatory authorities may impose additional restrictions on the marketing of, or the manufacturing processes for, the particular product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients, or become subject to fines, injunctions or the imposition of civil or criminal penalties;
- our reputation may suffer; and
- we could be required to develop a risk evaluation and mitigation strategies, or REMS, plan to prevent, monitor and/or manage a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event.

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

Inadequate funding for the FDA and other government agencies and/or potentially shifting priorities under the new presidential administration could hinder the FDA's and/or those other government agencies' ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products, provide feedback on clinical trials and development programs, meet with sponsors and otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels; ability to hire and retain key personnel and accept the payment of user fees; and statutory, regulatory, and policy changes, among other factors. Average review times at the FDA may fluctuate as a result. In addition, government funding of other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also increase the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or to otherwise respond to regulatory submissions, which would adversely affect our business. For example, the Trump Administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. Additionally, over the last several years, the U.S. government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough or reduce the number of critical FDA and other government employees and stop critical activities. If funding for the FDA is reduced, FDA priorities change or a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions which could have a material adverse effect on our business.

Additionally, we have in the past received grant funding from the National Institutes of Health, or NIH, and under the terms of previously awarded grants we expect to continue to receive grant funding from the NIH. Although we do not consider any of these grants material to our business, a prolonged impact on the availability of grant funding from government agencies could adversely impact our business.

Risks Related to our Financial Position and Need for Additional Capital

We are a development-stage company, and we expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Except for the year ended December 31, 2022, we have incurred significant operating losses since our inception. We incurred a net loss of $130.3 million and $77.4 million for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $822.4 million. To date, we have financed our operations primarily through public offerings and private placements of our securities, funding received from collaboration and license arrangements and a credit facility. We currently have no source of product revenue, and we do not expect to generate product revenue for the foreseeable future. We expect to devote substantially all of our financial resources and efforts to developing our mRNA-based therapies for the treatment of autoimmune diseases, identifying potential product candidates and conducting preclinical studies and our clinical trials. We are in the early stages of clinical development of most of our product candidates. We expect to

continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses will increase substantially as we:

- continue the research and development of our product candidates;
- increase and develop our manufacturing and distribution capacities;
- discover and develop additional product candidates;
- seek to maintain and enter into collaboration, licensing and other agreements, including, but not limited to research and development, and/or commercialization agreements;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale up internal manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts;
- experience any delays or encounter any issues with any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory, manufacturing or scale-up challenges; and
- are exposed to broad macroeconomic conditions including inflation and supply chain tightness which could result in us paying more, or being unable, to access goods and services.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval and securing reimbursement for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, and establishing and managing our collaborations at various stages of a product candidate's development. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical and biological 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. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and product revenue could be further delayed.

We may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations.

We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed and on terms favorable to us, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development for other product candidates. Additionally, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding to continue operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our clinical trials, our other research and development programs or any future commercialization efforts.

We believe that our existing cash, cash equivalents and restricted cash as of December 31, 2025, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We may pursue additional cash resources through public or private equity or debt financings, by establishing collaborations with other companies or through the monetization of potential royalty and/or milestone payments pursuant to our existing collaboration and license arrangements. Management's expectations with respect to our ability to fund current and long-term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no

guarantee that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations, meet long-term obligations or otherwise capitalize on our commercialization of our product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our clinical trials, preclinical development, manufacturing, laboratory testing and logistics;
- the number of product candidates that we pursue and the speed with which we pursue development;
- our headcount growth and associated costs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Market volatility resulting from the ongoing conflicts in Ukraine and the Middle East and current global macroeconomic conditions or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, including our clinical trial programs, or the commercialization of any product candidates, or be unable to sustain or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Our ability to use our net operating loss and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

We have net operating loss carryforwards, or NOLs, for federal and state income tax purposes that may be available to offset our future taxable income, if any. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs to offset future taxable income. If the IRS, challenges our analysis that existing NOLs will not expire before utilization due to previous ownership changes, or if we undergo an ownership change, our ability to use our NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code.

Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. As a result, we may not be able to use a material portion of the NOLs reflected on our balance sheet, even if we attain profitability.

Under current law, NOLs that arose before January 1, 2018 may be carried forward up to 20 years. NOLs that arose after 2017 may be used to offset at most 80% of our taxable income to the extent not offset by pre-2018 NOLs and such NOLs can be carried forward indefinitely. As a result, we may become required to pay federal income taxes in future years despite having generated losses for federal income tax purposes in prior years.

We have recorded a material amount of goodwill and indefinite-lived intangible assets in connection with the Merger. We have, and may in the future, record impairment charges, which would adversely impact our financial position and results of operations.

We have recorded a material amount of goodwill and indefinite-lived intangible assets on our balance sheet in connection with the Merger. We review our goodwill and intangible assets for impairment at least annually, or whenever events or changes in circumstances indicate that the carrying amounts of these assets may not be recoverable, in accordance with Accounting Standards Codification Topic 350, Intangibles - Goodwill and Other.

One potential indicator of goodwill impairment is whether the fair value of our equity, as measured by our market capitalization, is below the net book value of our equity. Whether our market capitalization triggers an impairment charge in any future period will depend on the underlying reasons for the decline in stock price, the significance of the decline and the length of time the stock price has been trading at such prices.

In addition, the determination as to whether our indefinite-lived intangible assets related to Descartes-08 are impaired is heavily dependent on the results of our ongoing clinical trials, as well as other factors, such as the potential market for Descartes-08, if approved. For example, during the year ended December 31, 2025, we recorded a $56.7 million impairment charge related to Descartes-08 in SLE, due to our announced pause in further development of Descartes-08 in SLE, following which we made a further decision that we would no longer pursue the development of Descartes-08 in SLE. See Note 3, “Goodwill and Indefinite-Lived Intangible Assets” to our consolidated financial statements included elsewhere in this Annual Report for more information.

In the event that we determine in a future period that impairment exists for any reason, we would record an impairment charge, which could be material and which would reduce the underlying asset’s value in the period such determination is made, which would adversely impact our financial position and results of operations.

We have incurred substantial expenses related to the integration of Old Cartesian.

We have incurred substantial expenses in connection with the Merger and the subsequent integration of Old Cartesian with Selecta. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including purchasing, accounting and finance, sales, billing, payroll, research and development, marketing and benefits. Both we and Old Cartesian have incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement and significant severance expenses as a result of the Merger. While we and Old Cartesian have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that have been and will be incurred are, by their nature, difficult to estimate accurately. These integration expenses have resulted in our taking significant charges against earnings following the completion of the Merger, and the amount and timing of such charges are uncertain at present.

Risks Related to Manufacturing and our Dependence on Third-Parties

We expect to continue to grow our manufacturing capabilities and resources and we must incur significant costs to develop this expertise and/or rely on third-parties to manufacture our products.

We have growing manufacturing capabilities, and in order to continue to develop our current product candidates, apply for regulatory approvals and, if approved, commercialize future products, we will need to continue to develop, contract for, or otherwise arrange for any necessary external manufacturing capabilities.

We manufacture our product candidates internally. There are risks inherent in biological manufacturing and we may not meet our delivery time requirements or provide adequate amounts of material to meet our needs, and we may make errors in manufacturing, any of which could delay our clinical trials and result in additional expense to us.

Our autologous cell therapy product candidates, including Descartes-08, are made on a patient-by-patient basis, rendering their manufacture less predictable and requiring more demanding logistics.

We rely on one or more third-party laboratories to perform certain quality control tests. These laboratories could become unavailable, or provision of their services could be delayed.

Additionally, as we scale up our manufacturing, we may encounter further challenges. Furthermore, competition for supply from our manufacturers from other companies, a breach or violation by such manufacturers of their contractual or regulatory obligations or a dispute with such manufacturers would cause delays in our discovery and development efforts, as well as additional expense to us.

In developing manufacturing capabilities by building our own manufacturing facilities, we have incurred substantial expenditures, and expect to incur significant additional expenditures in the future. Also, we have had to, and will likely need to continue to recruit, hire, and train qualified employees to staff our facilities. If we are unable to manufacture sufficient quantities of material or if we encounter problems with our facilities in the future, we may also need to secure alternative suppliers, and such alternative suppliers may not be available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner. In addition, to the extent we or our partners rely on contract manufacturing organizations, or CMOs, to supply our product candidates, any delays or disruptions in supply could have a material adverse impact on the research and development activities and potential commercialization of our or our partners' product candidates.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval process and we will need to meet, or will need to contract with CMOs who can meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. Our failure or the failure of any CMO to meet required regulatory authority requirements could result in the delayed submission of regulatory applications, or delays in receiving regulatory approval for any of our or our current or future collaborators' product candidates.

To the extent that we have existing, or enter into future, manufacturing arrangements with third-parties, we depend, and will depend in the future, on these third-parties to perform their obligations in a timely manner and consistent with contractual and regulatory requirements, including those related to quality control and quality assurance. The failure of any CMO to perform its obligations as expected, or, to the extent we manufacture all or a portion of our product candidates ourselves, our failure to execute on our manufacturing requirements, could adversely affect our business in a number of ways, including:

- we or our current or future collaborators may not be able to initiate or continue clinical trials of product candidates that are under development;
- we or our current or future collaborators may be delayed in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- we may lose the cooperation of our collaborators;
- our facilities and those of our CMOs, and our products could be the subject of inspections by regulatory authorities that could have a negative outcome and result in delays in supply;
- we may be required to cease distribution or recall some or all batches of our products or take action to recover clinical trial material from clinical trial sites; and
- ultimately, we may not be able to meet the clinical and commercial demands for our products.

We rely, and expect to continue to rely, on third-parties to conduct our clinical trials, and those third-parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials.

We rely, and expect to continue to rely, on third-parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials, including our current and planned Phase 3 clinical trials of Descartes-08. We also expect to rely on other third-parties to store and distribute drug supplies for our clinical trials.

While we rely on these third-parties for research and development activities, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP regulations, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials. If we or any of our CROs or third-party contractors fail to comply with applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, www.ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Furthermore, these third-parties may also have relationships with other entities, some of which may be our competitors. If these third-parties do not successfully carry out their contractual duties, do not comply with confidentiality obligations, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third-parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated, or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates or in commercializing our product candidates.

Risks Related to Commercialization of our Product Candidates and Legal Compliance Matters

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to manufacture and distribute cell therapies in a timely and secure manner;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

We currently have no sales organization. If we are unable to establish effective sales, marketing and distribution capabilities, or enter into agreements with third-parties with such capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third-parties to perform sales and marketing functions and we may not be successful in doing so. We expect to build a focused sales and marketing infrastructure to market or co-promote our product candidates in the United States and potentially elsewhere, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We face substantial competition, including from biosimilars, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug and biologic products and technologies is highly competitive and is characterized by rapid and substantial technological development and product innovations. We are aware that pharmaceutical and biotechnology companies, offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target, as well as smaller, early-stage companies, that offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target. We face competition with respect to our current product candidates and will face competition with respect to

any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement for product candidates and in marketing approved products than we do.

These third-parties compete with us in recruiting and retaining qualified scientific, sales and marketing 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 our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a cell therapy product that will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products.

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

The BPCIA was enacted as part of the ACA to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is still being interpreted and implemented by the FDA, and as a result, its ultimate impact, implementation, and meaning are subject to uncertainty. However, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any product candidate approved in the United States 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 the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Even if we are able to commercialize any of our product candidates, the products may become subject to unfavorable pricing regulations or third-party coverage or reimbursement policies, any of which would have a material adverse effect on our business.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval, especially novel products like our cell therapy product candidates, and may be particularly difficult because of the higher prices associated with such product candidates. Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if we will obtain an adequate level of reimbursement for our products by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and question the coverage of, and challenge the prices charged for, products. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Third-party payors often require that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. Some third-party payors may require pre-approval of coverage for new and innovative therapies, such as our product candidates, before they will provide reimbursement. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary for a specific indication or cost-effective, or that coverage or an adequate level of reimbursement will be available.

Moreover, there is heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills 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 drug products. There can be no assurance that our product candidates, will not be subject to heightened governmental scrutiny, unfavorable regulatory inquiry or action, or Congressional inquiry.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- loss of clinical trial participants or increased difficulty in enrolling future participants;
- significant costs to defend the related litigation or to reach a settlement;
- substantial payments to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy;
- the inability to commercialize any products that we may develop;
- distraction of management’s attention from our primary business; and
- substantial monetary awards to patients or other claimants.

We maintain general liability, product liability and umbrella liability insurance. Our existing insurance coverage may not fully cover potential liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical

trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Arrangements with physicians, others who may be in a position to generate business for us, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent. Private individuals (e.g., whistleblowers) can bring these actions on behalf of the 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 False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which also impose obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, or the Sunshine Act, which requires applicable manufacturers of certain products for which payment is available under a federal healthcare program to report annually to the government information related to certain payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members;
- analogous state 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 third-party payors, including private insurers; and requirements to comply with federal and pharmaceutical industry compliance guidelines;
- state data privacy and price transparency laws, many of which differ from each other in significant ways and often are broader than and not preempted by HIPAA or the Sunshine Act, thus complicating compliance efforts; by way of example, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context; and
- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the GDPR, which imposes obligations and restrictions on the collection and use of

personal data relating to individuals located in the EU (including health data); in addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Efforts to ensure that our business arrangements with third-parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and/or prescribe our product candidates, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, the ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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 to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, or if global health concerns were to again 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.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations administered by the U.S. Commerce Department's Bureau of Industry and Security, U.S. customs regulations, various economic and trade sanctions regulations including those administered or enforced by relevant government authorities, such as by the U.S. Treasury Department's Office of Foreign Assets Control or the U.S. Department of State, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism, or PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. U.S. sanctions laws and regulations may govern or restrict our business and activities in certain countries and with certain persons. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third-parties for clinical trials outside of the United States, to sell our product candidates abroad once 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, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Our 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.

If we or third-parties we rely upon fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and our contract manufacturers and other third-parties with whom we do business are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including biological materials and chemicals. Our operations also produce hazardous waste products. We generally contract with third-parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, 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. These current or future laws and regulations may impair our research, development or production efforts. The failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to our Intellectual Property

If we or our licensors are unable to adequately protect our proprietary technology, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would negatively impact our business.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and product candidates. 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.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. As we reach the statutory deadlines for deciding whether and where to initiate prosecution in specific foreign jurisdictions by filing national stage applications based on our Patent Cooperation Treaty, or PCT, applications, we will have to decide whether and where to pursue patent protection for the various inventions claimed in our patent portfolio, and we will only have the opportunity to

obtain patents in those jurisdictions where we pursue protection. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation, filing or prosecution of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form, preparation filing or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. We also cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, we have obligations under our licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

Some of our patent licenses are non-exclusive. In those cases, a competitor could obtain a license to the same or similar technology from the licensor. We have at least one exclusive patent license that is restricted to a particular field of use. A competitor could obtain a license to a similar technology outside of that field of use.

We cannot provide any assurances that the issued patents we currently own, or any future patents, include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage.

Further, it is possible that a patent claim may provide coverage for some but not all parts of a product candidate or third-party product. These and other factors may provide opportunities for our competitors to design around our patents.

Moreover, other parties may have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications, and may have received or may receive patents that may overlap or conflict with our patent applications or patents, either by claiming similar methods or by claiming subject matter that could dominate our patent position. In addition, it may be some time before we understand how patent offices react to our patent claims and whether they identify prior art of relevance that we have not already considered.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we have licensed or may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or other patent office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third-parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference or a derivation proceeding can result in our inability to receive, or a a third party receiving, the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to

obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent's validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although we require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors and any other third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how, and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how, and other information and technology. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business and operations.

Any litigation to enforce or defend our patent rights or other intellectual property rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be adversely affected.

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. 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. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. 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. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act America Invents Act, or the Leahy-Smith Act, included provisions that affect the way patent applications are prosecuted and may also affect patent litigation, including first-to-file provisions. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of

the time from invention to filing of a patent application. Thus, for our U.S. patent applications containing a priority claim after March 16, 2013, the date such provisions became effective, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre-Leahy-Smith Act law and regulations, while other patents applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy-Smith Act. This introduces additional complexities into the prosecution and management of our portfolio.

In addition, the Leahy-Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court 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 federal court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, 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. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, and any such changes could have a negative impact on our business.

Depending on these and other decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that have issued or may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that have issued or may issue in procedures in the USPTO or in courts.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third-party's intellectual property rights, we cannot guarantee that our technology, product candidates or use of our product candidates do not infringe third-party patents.

We are aware of numerous patents and pending applications owned by third parties, and we monitor patents and patent applications in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, to infringe a third party's intellectual property rights, we could be required or may choose to obtain a license from such third-party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if we are successful in such proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. 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.

Any of these risks coming to fruition could have a material adverse impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, and our issued patents covering our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, or failure to claim patent-eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents including claimes in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, 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 defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business and results of operations will be adversely affected.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under patents and patent applications that we own, to develop our product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and 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. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program, and our business and financial condition could suffer.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities.

Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Our or other relevant assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third-parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third-party, such as an employer, and thus, that the third-party has an ownership interest in the intellectual property arising out of work performed for us.

Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. In this regard, in addition to the United States, we also seek to protect our intellectual property rights in other countries. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidate, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe provide coverage for our lead product candidate, we will need to decide whether and where to pursue additional protection outside the United States. In addition, the laws of some foreign countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, for our existing patent rights outside the United States and any foreign patent rights we may decide to pursue in the future, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain 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 in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

If we do not obtain additional protection under the Hatch-Waxman Act and similar foreign legislation extending the terms of our patents for our product candidates, our business may be harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Patent term restorations, however, are limited to a maximum of five years and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It may take at least several months to a few years to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened, our competitors may obtain earlier approval of competing products and our ability to generate revenues could be materially adversely affected.

Risks Related to our Operations

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

We are highly dependent on Carsten Brunn, Ph.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific, clinical, and manufacturing teams. Although we have entered into employment agreements or offer letters with Dr. Brunn and other executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, technology and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an

extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We have incurred increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or Section 404 of the Sarbanes-Oxley Act of 2002. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

For example, in connection with the audit of our financial statements for the year ended December 31, 2023, we identified a material weakness in our internal control over financial reporting. As of December 31, 2024, this material weakness has been remediated, but we may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.

A variety of risks associated with winding down operations of our subsidiary in Russia or expanding operations internationally could adversely affect our business.

In addition to our U.S. operations, we maintain a wholly owned subsidiary in Russia, Selecta (RUS). We are in the process of winding down the operations of our subsidiary in Russia, but until that process is complete, we remain subject to risks associated with this subsidiary, or with any international operations, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax and labor conditions, and risks associated with our compliance with evolving international sanctions, which could harm our business. We may also rely on collaborators to commercialize any approved product candidates outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection of and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple-payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations, which could result in increased operating expenses and reduced revenues;

- natural disasters, political and economic instability, including wars, events of terrorism and political unrest, outbreak of disease, including pandemics, boycotts, curtailment of trade and other business restrictions, economic sanctions, and economic weakness, including inflation;
- changes in diplomatic and trade relationships;
- challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- restriction on cross-border investment, including enhanced oversight by the Committee on Foreign Investment in the United States and substantial restrictions on investment from China;
- certain expenses including, among others, expenses for travel, translation and insurance;
- legal risks, including use of the legal system by the government to benefit itself or affiliated entities at our expense, including expropriation of property;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA its books and records provisions, or its anti-bribery provisions; and
- risks that we may suffer reputational harm as a result of our operations in Russia.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

Our business and operations, including our development programs, could be materially disrupted in the event of system failures, security breaches, violations of data protection laws or data loss or damage by us or third-parties on which we rely, including our CROs or other contractors or consultants.

Our internal computer systems and those of third-parties on which we rely, including our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could have a material adverse effect on our business operations, including a material disruption of our development programs. Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third-parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates would likely result in delays in our marketing approval efforts and significantly increased costs in an effort to recover or reproduce the data.

We have previously been, and expect to remain, the target of cyber-attacks. As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks, such as ransomware attacks, and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These incidents pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third-parties on whose systems we rely for the conduct of our business. While we do not believe the effect of these incidents has historically been material to our results of operations, financial condition or prospects, cyber threats are persistent and constantly evolving. Such threats have increased in frequency, scope and potential impact in recent years, which increases the difficulty of detecting and successfully defending against them. As cyber threats continue to evolve, we may be required to incur additional expenses in order to enhance our protective measures or to remediate any information security vulnerability. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or destruction or loss of data and may incur significant additional expense to implement further data protection measures. It is also possible that unauthorized access to data may be obtained through inadequate use of security controls by our suppliers or other vendors.

Although we have general liability insurance coverage, our insurance may not cover all claims, continue to be available on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, product candidates or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unexpected liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the expected benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Risks Related to our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The trading price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you purchased. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results or progress, or changes in approach or timelines, of clinical trials of our product candidates or those of our competitors;
- failure or discontinuation of any of our development programs;
- commencement of, termination of, or any development related to any collaboration or licensing arrangement;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;

- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- announcement or market expectation of additional financing efforts;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates, projections or development timelines of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- sale of common stock by us or our stockholders in the future as well as the overall trading volume of our common stock;
- changes in the composition of our stockholder base;
- activity in the options market for shares of our common stock;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

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

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 67.1% of our outstanding voting stock as of December 31, 2025, assuming the conversion of all shares of all outstanding shares of Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, or Series A Preferred Stock, and Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share, or Series B Preferred Stock, into common stock, or 59.7%, assuming no conversion of outstanding shares of Series A Preferred Stock and Series B Preferred Stock into common stock. As a result, if some or all of these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

Anti-takeover provisions in our charter documents and under Delaware law and the terms of some of our contracts could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our restated certificate of incorporation, as amended, or the Charter, and amended and restated by-laws may delay or prevent an acquisition or a change in management. These provisions include a prohibition on actions by written consent of our stockholders and the ability of our board of directors, or the Board of Directors, to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us.

Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove

then current management by making it more difficult for stockholders to replace members of the Board of Directors, which is responsible for appointing the members of management.

Furthermore, our Charter specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders. This provision of our Charter applies to actions arising under the Securities Act and the Exchange Act. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents and may result in increased litigation costs for our stockholders. We note that there is uncertainty as to whether a court would enforce these provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act generally creates concurrent jurisdiction for state and federal courts over suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

We have been in the past and may in the future be subject to stockholder litigation.

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

On February 21, 2024, Paul Wymer, a purported stockholder of our Company, filed an action against us and members of our Board of Directors in the U.S. District Court for the Southern District of New York, titled Wymer v. Cartesian Therapeutics, Inc., et al., No. 24-cv-01288. The complaint alleged that the defendants violated Sections 14(a) and 20(a) of the Exchange Act by failing to disclose purportedly material information to our stockholders in our Preliminary and Definitive Proxy Statements filed on January 31, 2024, and February 14, 2024, respectively, in connection with the solicitation of stockholder approval of a proposal to convert our Series A Preferred Stock into our common stock, subject to certain beneficial ownership limitations, or the Series A Conversion Proposal. The complaint sought injunctive relief enjoining or rescinding the Merger, issuance of an amended proxy statement, and attorneys' fees and costs. Additional similar lawsuits may be filed. This action was subsequently dismissed on March 11, 2024.

On February 7, 2024, Justin Sloan, a purported stockholder of our Company, filed a putative class action on behalf of himself and similarly situated stockholders of the Company against our Company and members of our Board of Directors in the Court of Chancery of the State of Delaware, titled Sloan v. Barabe, et al., No. 2024-0105. The complaint alleged that the individual defendants breached their fiduciary duties by failing to disclose purportedly material information to our Company's stockholders in our Preliminary Proxy Statement filed on January 31, 2024 in connection with the solicitation of stockholder approval of the Series A Conversion Proposal. The complaint sought a temporary injunction against the stockholder vote on the Series A Conversion Proposal, compensatory damages, pre-and post-judgment interest, and attorneys' fees and costs. At a telephonic hearing on February 28, 2024, the Court denied the Plaintiff's motion to expedite the proceedings, rejecting Plaintiff's argument that the lawsuit raised colorable disclosure claims warranting expedited treatment. Additional similar lawsuits may be filed. This action was subsequently dismissed on March 13, 2024.

On August 3, 2020, a stockholder of Selecta filed a stockholder derivative action, purportedly on behalf of Selecta and against certain current and former members of the Company's Board of Directors, as well as one affiliated company owned by a current board member, in the Court of Chancery of the State of Delaware, namely Franchi v. Barabe, et al. The complaint alleged that the individual defendants breached their fiduciary duties and committed corporate waste when they authorized a private placement transaction, announced on December 19, 2019, at a price allegedly below fair value. The complaint further alleges that the four defendant directors who participated in the private placement were unjustly enriched in connection with the transaction. On September 25, 2020, the defendants filed a motion to dismiss the lawsuit. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021. On December 31, 2020, we received a litigation demand letter from two other putative stockholders relating to the same private placement transaction. On April 12, 2021, the Court of Chancery in the State of Delaware granted a motion to stay the litigation pending a review by a Special Committee appointed by the Company's Board of Directors. While the litigation was stayed, the parties reached an agreement in principle to settle the matter, and on March 18, 2022, they submitted a Stipulation and Agreement of Settlement and other documentation to the Court for its approval of the settlement. On July 21, 2022, the Court held a settlement hearing, at which the settlement was approved. On August 1, 2022, the Court entered an Order and Final Judgment which dismissed the action, and all claims contained therein, with prejudice. We could receive other demands or be subject to other litigation. We intend to vigorously defend against any demands which we believe to be without merit.

There can be no assurance as to the outcome of any stockholder litigation. Unfavorable outcomes in class action litigation could require us to pay extensive damages, which could delay or prevent our ability to develop our product candidates and harm our operations.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

One of the key responsibilities of our Board of Directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our Board of Directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our Board of Directors administers its cybersecurity risk oversight function directly and through the Audit Committee, which conducts regular risk assessments related to all matters affecting the enterprise, including cybersecurity, and receives periodic reports on the Company's cybersecurity risks and activities. Our Chief Financial Officer and our Senior Director, Head of IT are the Company employees responsible for developing and implementing a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. We partner with external cybersecurity vendors to enact a layered defense approach with controls deployed that seek to meet the requirements of the NIST Cybersecurity Framework.

Our Chief Financial Officer has served as a biotechnology executive for over 20 years, whose responsibilities have included direct oversight of his companies' cybersecurity risks. Our Senior Director, Head of IT has served as an Information Technology professional for over fifteen years and has held senior IT positions across several companies including a large pharmaceutical company.

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. Our Senior Director, Head of IT oversees the cybersecurity program through risk management, employee security training, and oversight and escalation of threat monitoring and incident response. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. In the event of a major security incident, we have established an escalation path for stakeholder notification and remediation efforts, and major incidents are immediately escalated to the Head of IT, Chief Financial Officer, and Chief Operations Officer. In 2024, an external partner conducted a robust cybersecurity assessment to evaluate our risk profile. We are leveraging these insights to strengthen our key defenses and continuously mature our security posture. We have implemented processes when evaluating third-party service providers, for example by reviewing available audit reports including the System and Organization Controls (SOC 2) reports and requesting disclosure of any previous cybersecurity events. We also perform quality audits of our regulated vendors, which includes an assessment of the vendor's information technology system and associated controls.

Additionally, we conduct periodic risk assessments to identify and monitor against potential cybersecurity threats and incidents, as well as assess for any changes in our business practices that may affect our cybersecurity position. This risk oversight includes identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks and address any identified gaps in existing safeguards. Primary responsibility for assessing, monitoring and managing our cybersecurity program is delegated to our Senior Director, Head of IT, who reports on IT operations, risk mitigation and assessment efforts, and other general cybersecurity matters to our Chief Financial Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards.

We continue to work with third-party cybersecurity vendors to assist us in best practices for implementing strengthened cybersecurity procedures. All Company employees and third-party vendors are instructed to promptly report any suspected breach of its security measures that may affect our Company to the Senior Director, Head of IT. Our Chief Financial Officer and Senior Director, Head of IT provide periodic briefings to the Audit Committee regarding our Company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third-parties, and related matters. The Audit Committee provides regular updates to the full Board of Directors on such reports.

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this Annual Report on Form 10-K.

Item 2. Properties

Our corporate headquarters are currently located at 7495 New Horizon Way, Frederick, Maryland and consists of over 35,000 total square feet of integrated manufacturing and office space under a lease that expires in June 2031. Additionally, we lease approximately 7,909 total square feet of office, laboratory, and manufacturing space in Gaithersburg, Maryland under a lease that expires in January 2027 and 32,294 total square feet of office and laboratory space in Watertown, Massachusetts under a lease that expires in May 2028.

Item 3. Legal Proceedings

None.

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 publicly traded on The Nasdaq Stock Market under the symbol "RNAC".

Holders

As of February 28, 2026, there were 26,509,024 shares of our common stock outstanding held by approximately 102 holders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividends

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 and expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the Board of Directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans in Item 12 of Part III of this Annual Report is incorporated herein by reference. Any future determination to pay dividends will be made at the discretion of our Board of Directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our Board of Directors. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

We did not repurchase any of our equity securities during the quarter ended December 31, 2025.

Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

Not applicable.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes thereto and other financial information included elsewhere in this Annual Report. In addition to historical information, some of the information contained in the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should review the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a late clinical-stage biotechnology company pioneering cell therapy for the treatment of autoimmune diseases. We leverage our proprietary technology and manufacturing platform to introduce mRNA into cells to provide a therapeutic effect to patients suffering from a variety of autoimmune conditions. Unlike DNA, mRNA degrades naturally over time without integrating into the cell's genetic material. Our cell therapies are designed to be dosed repeatedly like conventional drugs, administered in an outpatient setting, and given without pre-treatment chemotherapy, which is required with many conventional cell therapies.

Merger

On November 13, 2023, the Company (formerly known as Selecta) merged with the private Delaware corporation which, immediately prior to the Merger, was known as Cartesian Therapeutics, Inc., in accordance with the terms of the Merger Agreement, by and among Selecta, First Merger Sub, Second Merger Sub, and Old Cartesian. Pursuant to the Merger Agreement, First Merger Sub merged with and into Old Cartesian, pursuant to which Old Cartesian was the surviving corporation and became a wholly owned subsidiary of Selecta. Immediately following the First Merger, Old Cartesian merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity. In connection with the Second Merger, Old Cartesian changed its name to Cartesian Bio, LLC. In connection with the Merger and pursuant to the Merger Agreement, the Company changed its corporate name to Cartesian Therapeutics, Inc. See Note 4, "Merger" to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 for more information regarding the Merger.

Financial Operations

To date, we have financed our operations primarily through public offerings and private placements of our securities, funding received from research grants, collaboration and license arrangements and a credit facility. We do not have any products approved for sale and have not generated any product sales.

We incurred a net loss of $130.3 million and $77.4 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $822.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we:

- continue to advance Descartes-08 for MG through Phase 3 development;
- advance Descartes-08 for myositis into Phase 2 development;
- continue to develop our preclinical and clinical-stage product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements;
- hire additional staff, including clinical, scientific and management personnel; and
- incur additional costs associated with continuing to operate as a public company.

Until we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and license and collaboration agreements. We may be unable to raise capital when needed or on reasonable terms, if at all, which would force us to delay, limit, reduce or terminate our product development or future commercialization efforts. We will need to generate significant revenues to achieve profitability, and we may never do so.

Concurrently with the closing of the Merger, we entered into a securities purchase agreement, or the 2023 Securities Purchase Agreement, pursuant to which we agreed to issue 149,330.115 shares of Series A Preferred Stock, in exchange for aggregate gross proceeds of $60.25 million, or the 2023 Private Placement. We granted customary registration rights to investors in connection with the 2023 Private Placement.

We believe that our existing cash, cash equivalents, and restricted cash as of December 31, 2025 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

The consolidated financial information presented below includes the accounts of Cartesian Therapeutics, Inc. and our wholly owned subsidiaries, Selecta (RUS) LLC, a Russian limited liability company, or Selecta (RUS), Selecta Biosciences Security Corporation, a Massachusetts securities corporation which was dissolved in December 2024, and Cartesian Bio, LLC, a Delaware limited liability company, which is a variable interest entity for which we are the primary beneficiary. All intercompany accounts and transactions have been eliminated.

Components of our Results of Operations

Collaboration and license revenue

To date, we have not generated any revenue from product sales. Our revenue consists primarily of collaboration and license revenue, which includes amounts recognized related to upfront and milestone payments for research and development funding under collaboration and license agreements. We expect that any revenue we generate will fluctuate from quarter to quarter

because of the timing and amounts of fees, research and development reimbursements and other payments from collaborators. We do not expect to generate revenue from product sales for at least the next several years. If we or our collaborators fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval as needed, our ability to generate future revenue will be harmed, and will affect the results of our operations and financial position. For further descriptions of the agreements underlying our collaboration and license revenue, see Notes 2, "Summary of Significant Accounting Policies" and 15, "Collaboration and License Agreements" to our consolidated financial statements included elsewhere in this Annual Report.

Grant revenue

We generate grant revenue, which consists of funding received to perform specific research and development services under grant arrangements.

Research and development expenses

Our research and development expenses consist of internal and external research and development costs, which primarily include fees paid to contract research organizations, internal manufacturing- and quality-related expenses, process development costs, internal research and development expenses, as well as fees paid to contract manufacturing organizations. These costs are primarily associated with compensation expenses for our research and development employees, capital equipment and supplies for our process development and manufacturing process, and other related expenses. Our internal research and development employees as well as our indirect costs are shared across multiple development programs and are not solely dedicated to individual programs.

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in clinical development generally have higher development costs than those in earlier stages of development, primarily due to the size, duration and cost of clinical trials. The successful development of our clinical and preclinical product candidates is highly uncertain. Clinical development timelines, the probability of success and development costs can differ materially from our expectations. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently expect will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time to complete any clinical development.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development and support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expenses, travel expenses for our general and administrative personnel and professional fees for auditing, tax and corporate legal services, including intellectual property-related legal services.

Impairment of indefinite-lived intangible and long-lived assets

Impairment of indefinite-lived intangible and long-lived assets consists of impairment charges on our intangible and long-lived assets.

Interest income

Interest income consists primarily of income earned on our cash, cash equivalents and marketable securities.

Gain on change in fair value of warrant liabilities

Common warrants classified as liabilities are remeasured quarterly at fair value with the change in fair value recognized as a component of earnings.

Loss on change in fair value of contingent value right liability

The contingent value right liability is remeasured quarterly at fair value with the change in fair value recognized as a component of earnings.

Loss on change in fair value of forward contract liabilities

The forward contract liabilities associated with the delayed issuance of the Series A Preferred Stock related to the Merger and 2023 Private Placement were remeasured upon settlement at fair value with the change in fair value recognized as a

component of earnings. The Series A Preferred Stock forward contract liability was settled during the year ended December 31, 2024

Other (expense) income, net

Other (expense) income, net consists of non-operating income and non-operating expenses, including impairment charge on investment.

Income taxes

We provide deferred tax assets and liabilities for the expected future tax consequences of temporary differences between our financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more-likely-than-not be realized.

We determine whether it is more likely than not that a tax position will be sustained upon examination. If it is not more-likely-than-not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. We account for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date,we have not incurred interest and penalties related to uncertain tax positions.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

	Year Ended December 31,			
	2025	2024	Increase (Decrease)	
	(in thousands, except percentages)			
Revenues:				
Collaboration and license	$ 400	$ 38,275	$ (37,875)	(99)%
Grant	2,397	638	1,759	NM
Total revenues	2,797	38,913	(36,116)	(93)%
Operating expenses:				
Research and development	58,034	45,105	12,929	29 %
General and administrative	31,468	30,126	1,342	4 %
Impairment of indefinite-lived intangible and long-lived assets	56,700	7,579	49,121	NM
Total operating expenses	146,202	82,810	63,392	77 %
Operating loss	(143,405)	(43,897)	(99,508)	NM
Other income (expense):				
Interest income	6,579	7,386	(807)	(11)%
Gain on change in fair value of warrant liabilities	3,695	2,558	1,137	44 %
Loss on change in fair value of contingent value right liability	(4,354)	(36,900)	32,546	(88)%
Loss on change in fair value of forward contract liabilities	—	(6,890)	6,890	(100)%
Other (expense) income, net	(2,010)	606	(2,616)	NM
Total other income (expense), net	3,910	(33,240)	37,150	(112)%
Loss before income taxes	(139,495)	(77,137)	(62,358)	81 %
Income tax benefit (expense)	9,193	(287)	9,480	NM
Net loss	$ (130,302)	$ (77,424)	$ (52,878)	68 %

NM - Not meaningful

Collaboration and license revenue

During the year ended December 31, 2025, we recognized $0.4 million of collaboration and license revenue, compared to $38.3 million for the year ended December 31, 2024, a decrease of $37.9 million. The decrease was primarily due to revenue recognized under the Sobi License in the prior year, resulting from the $30.0 million unconstrained development milestone, coupled with recognition of the remaining deferred revenue under the License and Development Agreement, or the Astellas Agreement, with Audentes Therapeutics, Inc., or Astellas, upon notice of termination during the year ended December 31, 2024.

Grant revenue

During the year ended December 31, 2025, we recognized $2.4 million of grant revenue, compared to $0.6 million for the year ended December 31, 2024, an increase of $1.8 million. The increase was primarily due to increased expenses reimbursable under the grant from the National Institute of Neurological Disorders and Stroke of the National Institutes of Health incurred during the year ended December 31, 2025, for which we received funding approval during the year ended December 31, 2024.

Research and development expenses

The following is a comparison of research and development expenses for the years ended December 31, 2025 and 2024 (in thousands, except percentages):

	Year Ended December 31,			
	2025	2024	Increase (Decrease)	
Legacy Selecta programs	$ —	$ 6,150	$ (6,150)	(100)%
Descartes-08 for MG	22,893	12,142	10,751	89 %
Early stage programs	5,795	1,028	4,767	NM
Research and development employee expenses	16,826	11,952	4,874	41 %
Research and development stock-based compensation expense	4,772	3,217	1,555	48 %
Research and development facilities and other expenses	7,748	10,616	(2,868)	(27)%
Total research and development expenses	$ 58,034	$ 45,105	$ 12,929	29 %

NM - Not meaningful

For the year ended December 31, 2025, our research and development expenses were $58.0 million, compared to $45.1 million for the year ended December 31, 2024, an increase of $12.9 million. The increase was primarily due to an increase in expenses for the development of Descartes-08 for MG, primarily related to the expenses for the ongoing Phase 3 AURORA trial, an increase in our research and development employee expenses and stock-based compensation expense due to headcount growth and manufacturing operations expenses. These increases were partially offset by a decrease in expenses for legacy Selecta programs, primarily related to decreased expenses for Xork as a result of the termination of the Astellas Agreement in the year ended December 31, 2024 and a decrease in facilities and other expense, primarily driven by the move of costs associated with our leased office and laboratory space at 65 Grove Street, Watertown, Massachusetts moved to general and administrative expenses for the year ended December 31, 2025.

General and administrative expenses

For the year ended December 31, 2025, our general and administrative expenses were $31.5 million, compared to $30.1 million for the year ended December 31, 2024, an increase of $1.4 million. The increase was primarily due to an increase in facility and office costs, primarily as the result of the move of costs associated with our leased office and laboratory space at 65 Grove Street, Watertown, Massachusetts from research and development costs to general and administrative expenses, coupled with an increase in stock-based compensation, primarily driven by executive awards, and an increase in consulting expenses. These increases were partially offset by a decrease in professional fees, driven primarily by lower legal and audit fees, coupled with decreases in patent costs due to a smaller body of intellectual property work, and a decrease in salaries and benefits, driven by the retention bonus expense in the prior year.

Impairment of indefinite-lived intangible and long-lived assets

During the year ended December 31, 2025, we recorded a non-cash impairment charge of $56.7 million related to our in-process research and development, or IPR&D, asset related to Descartes-08 for SLE. See Note 3, “Goodwill and Indefinite-Lived Intangible Assets” for more information. During the year ended December 31, 2024, we recorded an impairment charge to our long-lived assets of $7.6 million after evaluating the right-of-use assets and related furniture and fixtures upon our decision to cease use of our office and laboratory space at 65 Grove Street, Watertown, Massachusetts.

Interest income

Interest income for the year ended December 31, 2025 was $6.6 million, compared to $7.4 million for the year ended December 31, 2024, a decrease of $0.8 million. The decrease in interest income was due to lower investment balances and lower interest rates.

Gain on change in fair value of warrant liabilities

For the year ended December 31, 2025, we recognized $3.7 million gain on the change in the fair value of warrant liabilities, compared to $2.6 million gain for the year ended December 31, 2024, an increase of $1.1 million. Fair value of warrant liabilities was determined utilizing the Black-Scholes valuation methodology. The decrease in warrant value was primarily driven by a decrease in the per-share price of our common stock and the passage of time.

Loss on change in fair value of contingent value right liability

For the year ended December 31, 2025, we recognized a $4.4 million loss on the change in the fair value of contingent value right liability, compared to a loss of $36.9 million for the year ended December 31, 2024, a decrease of $32.5 million. The fair values of the contingent value right liability as of December 31, 2025 and 2024 were determined utilizing a Monte Carlo simulation model. The increase in the fair value of the contingent value right liability was primarily due to the passage of time, partially offset by changes in the anticipated amount and timing of future payments.

Loss on change in fair value of forward contract liabilities

For the year ended December 31, 2024, we recognized $6.9 million loss on the change in fair value of Series A Preferred Stock forward contract liabilities. The Series A Preferred Stock forward contract liability was settled during the year ended December 31, 2024.

Other (expense) income, net

During the year ended December 31, 2025, we recognized other expense, net of $2.0 million, compared to $0.6 million of other income, net for the year ended December 31, 2024, a change of $2.6 million. The change was primarily driven by a loss on impairment of an investment during the year ended December 31, 2025, coupled with sublease income in the year ended December 31, 2024. The terms of our subleases expired during the year ended December 31, 2024.

Income taxes

During the year ended December 31, 2025, we recognized a $9.2 million tax benefit primarily related to impairment of IPR&D during the year and corresponding deferred tax liability. During the year ended December 31, 2024, we recognized a deferred tax expense of $0.3 million relating to a change in state tax rate applied to the indefinite deferred tax liability.

Liquidity and Capital Resources

Except for net income for the year ended December 31, 2022, we have incurred recurring net losses since our inception. We expect that we will continue to incur losses and that such losses will increase for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, third-party funding, potential royalty and/or milestone monetization transactions and other collaborations and strategic alliances.

Our cash, cash equivalents, and restricted cash were $126.9 million as of December 31, 2025, of which $1.7 million was restricted cash related to lease commitments.

In addition to our existing cash equivalents, we from time to time have received and may receive in the future research and development funding pursuant to our collaboration and license agreements. Currently, funding from payments under our collaboration agreements represent our only source of committed external funds.

The liability associated with the contingent value rights agreement, or CVR Agreement, entered into on December 6, 2023, will be settled solely through cash flow received under the Sobi License and any other Gross Proceeds (as such term is defined in the CVR Agreement) net of certain agreed deductions. Under the CVR Agreement, 100% of all milestone payments, royalties, and other amounts paid to us or our controlled entities under the Sobi License, and any other Gross Proceeds, in each case net of certain agreed deductions, will be distributed to holders of the CVRs. There is no contractual obligation for us to fund any amount related to the CVR liability.

Collaboration and License Agreements

In-licenses

In September 2023, we entered into the Biogen Agreement with Biogen to research, develop, make, use, offer, sell and import products or processes containing or using an engineering T-cell modified with an mRNA comprising, or encoding a protein comprising, certain sequences licensed under the Biogen Agreement for the prevention, treatment, palliation and management of autoimmune diseases and disorders, excluding cancers, neoplastic disorders, and paraneoplastic disorders. We are not obligated to pay Biogen any expenses, fees, or royalties. For further description of the Biogen Agreement, see Note 15, “Collaboration and License Agreements” to our consolidated financial statements included elsewhere in this Annual Report.

Effective September 2019, we entered into the NCI Agreement with NCI. Under the NCI Agreement, we were granted a license under certain NCI patents and patent applications designated in the agreement, to make, use, sell, offer and import products and processes within the scope of the patents and applications licensed under the NCI Agreement when developing and manufacturing anti-BCMA CAR-T cell products for the treatment of MG, pemphigus vulgaris, and immune

thrombocytopenic purpura according to methods designated in the NCI Agreement. In connection with our entry into the NCI Agreement, we paid to NCI a one-time $0.1 million license royalty payment. Under the NCI Agreement, we are further required to pay NCI a low five-digit annual royalty. We must also pay earned royalties on net sales in a low single-digit percentage and pay up to $0.8 million in benchmark royalties upon our achievement of designated benchmarks that are based on the commercial development plan agreed between the parties. For further description of the NCI Agreement, see Note 15, "Collaboration and License Agreements" to our consolidated financial statements included elsewhere in this Annual Report.

In October 2021, we entered into an Exclusive License Agreement with Genovis AB (publ.), or Genovis, or the Genovis Agreement, and paid Genovis a $4.0 million one-time upfront payment. In February 2023, as a result of the sublicense of Xork, a bacterial IgG protease, to Astellas, we made a $4.0 million payment to Genovis. The Genovis Agreement was terminated effective September 13, 2024. For further description of the Genovis Agreement, see Note 15, "Collaboration and License Agreements" to our consolidated financial statements included elsewhere in this Annual Report.

Out-licenses

In January 2023, we entered into the Astellas Agreement with Astellas. Under this agreement, Astellas obtained the sole and exclusive right to commercialize Xork for use in Pompe disease in combination with an Astellas gene therapy investigational or authorized product, with a current focus on AT845. In connection with entry into this agreement, we received a $10.0 million upfront payment and are eligible to receive $340.0 million for certain additional development and commercial milestones plus royalties on any potential commercial sales where Xork is used as a pre-treatment for AT845. As a result of the sublicense of Xork to Astellas, we made a $4.0 million payment to Genovis in February 2023. The Astellas Agreement was terminated effective June 6, 2024. For further description of the Astellas Agreement, see Note 13, "Revenue Arrangements" to our consolidated financial statements included elsewhere in this Annual Report. Amounts paid and remaining obligations with regard to the Xork product candidate not reimbursed by Astellas through the Astellas Agreement were subject to potential reimbursement through deductions to CVR distributions as described in Note 6, "Fair Value Measurements" to our consolidated financial statements included elsewhere in this Annual Report.

In June 2020, we entered into the Sobi License. Sobi paid us a one-time, upfront payment of $75.0 million, and upon the closing of a private placement of our common stock to Sobi at a price of $138.468 per share, we received an additional $25.0 million from Sobi. We are eligible to receive $630.0 million in milestone payments upon the achievement of various development and regulatory milestones and sales thresholds for annual net sales of NASP, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier. Sobi has agreed to fund the Phase 3 clinical program of NASP, which commenced in September 2020. In July 2022, we received $10.0 million for the completion of the enrollment of the DISSOLVE II trial. In July 2024, we received $30.0 million for the milestone associated with the initiation of a rolling biologics license application to the FDA for NASP for the potential treatment of chronic refractory gout by Sobi. Proceeds from milestone payments and royalties on sales of NASP, if any, are required to be distributed, net of certain agreed deductions, to holders of the CVRs. For further description of the Sobi License, see Note 13, "Revenue Arrangements" to our consolidated financial statements included elsewhere in this Annual Report.

Financings

On November 13, 2023, we entered into the 2023 Securities Purchase Agreement with (i) Timothy A. Springer, Ph.D., a member of our Board of Directors; (ii) TAS Partners LLC, an affiliate of Dr. Springer, and (iii) Seven One Eight Three Four Irrevocable Trust, a trust associated with Murat Kalayoglu, M.D., Ph.D., a co-founder and the former chief executive officer of Old Cartesian, who joined our Board of Directors effective immediately after the effective time of the Merger, providing for the 2023 Private Placement. In the 2023 Private Placement, we issued and sold an aggregate of 149,330.115 shares of Series A Preferred Stock for an aggregate purchase price of $60.25 million, of which 50,189.789 shares of Series A Preferred Stock were issued and sold in the year ended December 31, 2023 for gross proceeds of $20.25 million, and 99,140.326 shares of Series A Preferred Stock were issued and sold during the year ended December 31, 2024 for gross proceeds of $40.0 million.

On July 2, 2024, we entered into a securities purchase agreement, or the 2024 Securities Purchase Agreement, for a private investment in public equity financing, or the 2024 Private Placement, which provided for the issuance of 3,563,247 shares of common stock and 2,937,903 shares of Series B Preferred Stock, each at a purchase price of $20.00 per share. The 2024 Private Placement resulted in gross proceeds of approximately $130.0 million before deducting placement agent fees and other offering expenses. We granted customary registration rights to investors in connection with the 2024 Private Placement.

On December 13, 2024, we and Leerink Partners entered into a Sales Agreement, or the Sales Agreement. Under the Sales Agreement, we may issue and sell shares of our common stock, from time to time, through Leerink Partners for aggregate gross sales proceeds of up to $100.0 million. During the years ended December 31, 2025 and 2024, we sold no shares of our common stock pursuant to the Sales Agreement.

Future funding requirements

As of the date of this Annual Report, we have not generated any revenue from product sales. We do not know when, or if, we will generate revenue from product sales. We will not generate significant revenue from product sales unless and until we obtain regulatory approval and commercialize one of our current or future product candidates. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, milestone and royalty payments for in-licenses, and general overhead costs. We expect that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to risks in the development of our products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect that we will need substantial additional funding to support our continuing operations.

As of December 31, 2025, we had an accumulated deficit of $822.4 million. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates, conducting preclinical studies and clinical trials, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital.

We regularly evaluate various potential sources of additional funding such as strategic collaborations, license agreements, debt issuance, potential royalty and/or milestone monetization transactions and the issuance of equity instruments to fund our operations. If we raise additional funds through strategic collaborations and alliances, which may include existing collaboration partners, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. To the extent that we raise additional capital through the sale of equity instruments, the ownership interest of our existing stockholders will be diluted, and other preferences may be necessary that adversely affect the rights of existing stockholders.

We believe that our existing cash, cash equivalents, and restricted cash as of December 31, 2025 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We may pursue additional cash resources through public or private equity or debt financings, by establishing collaborations with other companies or through the monetization of potential royalty and/or milestone payments pursuant to our existing collaboration and license arrangements. Management's expectations with respect to our ability to fund current and long-term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations, meet long-term obligations or otherwise capitalize on our commercialization of our product candidates.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our clinical trials, preclinical development, manufacturing, laboratory testing and logistics;
- the number of product candidates that we pursue and the speed with which we pursue development;
- our headcount growth and associated costs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

Cash Requirements due to Contractual Obligations and Other Commitments

We are under agreement to lease approximately 32,294 square feet of laboratory and office space in Watertown, Massachusetts through May 2028. Remaining lease payments from December 31, 2025 through the end of the lease term total approximately $6.8 million. Payments made and remaining obligations on this lease liability were subject to potential reimbursement through deductions to CVR distributions as described in Note 6 “Fair Value Measurements” to our consolidated financial statements included elsewhere in this Annual Report and were reimbursed in the March 2025 CVR distribution.

In November 2023, in connection with the Merger, we acquired two leases for office and laboratory space in Gaithersburg, Maryland, which expire in January 2027. Annualized rent is approximately $0.3 million and remaining lease payments from December 31, 2025 through the end of the lease term total approximately $0.4 million.

In February 2024, we entered into an agreement to lease approximately 19,199 square feet of integrated manufacturing and office space in Frederick, Maryland. In May 2024, we entered into an amendment to lease an additional approximately 7,842 square feet at the same site. In August 2024, we entered into a second amendment to lease an additional approximately 2,009 square feet at the same site. In March 2025, we entered into a third amendment to lease an additional approximately 6,439 square feet at the same site. The leases expire coterminously in June 2031. Annualized base rent under the leases is approximately $1.4 million and is subject to annual increases in accordance with the terms of the lease agreement. Remaining lease payments from December 31, 2025 through the end of the lease term total approximately $8.8 million.

We are also party to certain license and collaboration agreements with Biogen, NCI, and Shenyang Sunshine Pharmaceutical Co., Ltd., or 3SBio. We may be obligated to make certain future payments which are contingent upon future events such as our achievement of specified regulatory and commercial milestones, or royalties on net product sales under these agreements. As of December 31, 2025, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. Payments made and remaining obligations on the license agreement with 3SBio are subject to potential reimbursement through deductions to CVR distributions as described in Note 6, “Fair Value Measurements” to our consolidated financial statements included elsewhere in this Annual Report.

Summary of Cash Flows

	Year Ended December 31,	
(In thousands)	**2025**	**2024**
Cash (used in) provided by:		
Operating activities	$ (73,941)	$ (23,674)
Investing activities	(5,454)	(8,742)
Financing activities	(8,055)	168,428
Effect of exchange rate changes on cash	45	(21)
Net change in cash, cash equivalents, and restricted cash	$ (87,405)	$ 135,991

Operating activities

Net cash used in operating activities for the year ended December 31, 2025 was $73.9 million compared to $23.7 million for the year ended December 31, 2024. The increase in net cash used in operating activities of $50.2 million was primarily due to $65.9 million of net loss, adjusted for non-cash items, and $8.0 million of cash used in changes in operating assets and liabilities during the year ended December 31, 2025 compared to $17.9 million of net loss, adjusted for non-cash items, and $5.8 million of cash provided by changes in operating assets and liabilities during the year ended December 31, 2024.

Investing activities

Net cash used in investing activities for the year ended December 31, 2025 was $5.5 million compared to net cash used in investing activities of $8.7 million for the year ended December 31, 2024, a decrease of $3.2 million. The net cash used in investing activities for the years ended December 31, 2025 and 2024 consisted primarily of purchases of property and equipment.

Financing activities

Net cash used in financing activities for the year ended December 31, 2025 was $8.1 million compared to net cash provided by financing activities of $168.4 million for the year ended December 31, 2024, a change of $176.5 million. The net cash used in financing activities for the year ended December 31, 2025 was primarily due to payment on the contingent value

right liability. The net cash provided by financing activities for the year ended December 31, 2024 was primarily the result of proceeds of the 2024 Private Placement and the 2023 Private Placement.

Recent Accounting Pronouncements

For a discussion of recently adopted or issued accounting pronouncements refer to Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements included elsewhere in this Annual Report.

Off-Balance Sheet Arrangements

As of December 31, 2025, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities in our consolidated financial statements. Actual results may differ from these estimates under different assumptions or conditions and could have a material impact on our reported results. While our significant accounting policies are more fully described in the notes to our consolidated financial statements included elsewhere in this Annual Report, we believe the following accounting policies to be the most critical in understanding the judgments and estimates we use in preparing our consolidated financial statements:

Contingent Value Right Liability

The CVRs distributed pursuant to the terms of the CVR Agreement represent financial instruments that are accounted for under the fair value option election in ASC Topic 825, *Financial Instruments (ASC 825)*. Under the fair value option election, the CVRs are initially measured at the aggregate estimated fair value of the CVRs and will be subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value of the CVR liability was determined using a Monte Carlo simulation model as of December 31, 2025 and 2024 to estimate future cash flows associated with the legacy assets, including the expected milestone and royalty payments under the Sobi License, net of deductions. Changes in fair value of the CVR liability are presented in the consolidated statements of operations and comprehensive loss. The liability value is based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of success, expected volatility of future revenues, which represent a Level 3 measurement within the fair value hierarchy.

Collaboration and License Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Pursuant to ASC Topic 606, Revenue from Contracts with Customers (ASC 606), a customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. If a promised good or service is not distinct, it is combined with other promised goods or services into a performance obligation. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Collaboration and License Revenue

We currently generate revenue through collaboration and license agreements with strategic collaborators for the development and commercialization of product candidates. Collaboration and license agreements with customers are generally accounted for in accordance with ASC 606. We analyze collaboration arrangements by first assessing whether they are within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808), and evaluate 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 that are dependent on the commercial success of such activities. Collaboration agreements with customers that are not within the scope of ASC 808 are accounted for in accordance with ASC 606. To the extent the collaboration agreement is within the scope of ASC 808, we also assess whether any aspects of the agreement are within the scope of other accounting literature (specifically ASC 606). If we conclude that some or all aspects of the agreement are distinct and represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC 606. We recognize the shared costs incurred that are not within the scope of other accounting literature as a component of the related expense in the period incurred by analogy to ASC Topic 730, Research and Development (ASC 730), and record reimbursements from counterparties as an offset to the related research and development costs. In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under the agreements in accordance with ASC 606, we perform the five steps above. As part of the accounting for the arrangement, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success. The assumptions used to determine the stand-alone selling price and our satisfaction of performance obligations have a material effect on our collaboration and license revenue and may prove to be wrong.

The terms of our arrangements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost-sharing of research and development expenses; and (v) profit/loss sharing arising from co-promotion arrangements.

Licenses of Intellectual Property

If the license to our intellectual property is determined to be distinct from the other promised goods and services identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If not distinct, the license is combined with other promised goods and services in the contract. For licenses that are combined with other promised goods and services, we assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Optional licenses are evaluated to determine if they are issued at a discount, and therefore, represent material rights and should be accounted for as separate performance obligations.

Milestone Payments: At the inception of each arrangement that includes developmental and regulatory milestone payments, we evaluate whether the achievement of each milestone specifically relates to our efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of our efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to our efforts to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. We also evaluate the milestone to determine whether they are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated, otherwise, such amounts are constrained and excluded from the transaction price. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the transaction price. Any such adjustments to the transaction price are allocated to the performance obligations on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation shall be recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

Manufacturing Supply Services: Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are evaluated to determine if they are distinct and optional. For optional services that are distinct, we assess if they are priced at a discount, and therefore, provide a material right to the licensee to be accounted for as separate performance obligations.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) in accordance with the royalty recognition constraint.

Clinical Trial Costs

Clinical trial expenses are a significant component of research and development expenses, and we outsource a significant portion of these costs to third-parties. Third-party clinical trial expenses include patient costs, clinical research organization

costs and costs for data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued clinical trial cost. These third-party agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. We also record accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by us materially affecting our results of operations. The historical clinical accrual estimates made by us have not been materially different from the actual costs.

Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of the identified net assets acquired as a result of our business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing at a reporting unit level on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired. An entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Such qualitative factors include macroeconomic conditions, industry and market considerations, cost factors, overall financial performance, certain assumptions that form the basis of forecasted results (e.g., revenue, discount rates and probability of clinical success) and other relevant events. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount.

We evaluate goodwill for impairment at least annually on October 1, or the Assessment Date, and whenever facts and circumstances indicate that their carrying amounts may not be recoverable.

Indefinite-Lived Intangible Assets

Indefinite-lived intangible assets consist of IPR&D. The fair values of IPR&D assets acquired in business combinations are capitalized. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. We consider many factors in evaluating whether the value of our intangible assets with indefinite lives may not be recoverable, including, but not limited to, expected growth rates, the cost of equity and debt capital, general economic conditions, our outlook and market performance of our industry and recent and forecasted financial performance.

We evaluate indefinite-lived intangible assets for impairment at least annually on the Assessment Date, and whenever facts and circumstances indicate that their carrying amounts may not be recoverable.

Warrant Liabilities

In December 2019, we issued the 2019 Warrants in connection with a securities purchase agreement between us and a group of institutional investors and certain members of our Board of Directors. Pursuant to the terms of the 2019 Warrants, we could have been required to settle the common warrants in cash in the event of certain acquisitions of us and, as a result, the 2019 Warrants were required to be measured at fair value and reported as a liability on the balance sheet. The outstanding 2019 Warrants expired on December 23, 2024 in accordance with their terms.

In April 2022, we issued warrants in connection with an underwritten offering of shares of common stock and warrants to purchase shares of common stock, or the 2022 Warrants. Pursuant to the terms of the 2022 Warrants, we could be required to settle the 2022 Warrants in cash in the event we are acquired under certain circumstances and, as a result, the 2022 Warrants are required to be measured at fair value and reported as a liability on the balance sheet.

We recorded the fair value of the 2019 Warrants and 2022 Warrants upon issuance using the Black-Scholes valuation model, and are required to revalue the common warrants at each reporting date and upon exercise or expiration with any

changes in fair value recorded on our statement of operations. In December 2022, we amended the terms of the outstanding 2019 Warrants held by certain members of our Board of Directors to remove the cash settlement provision (as so amended, the Amended 2019 Warrants). As a result, the Amended 2019 Warrants were remeasured at fair value on December 20, 2022 and reclassified from a liability to equity on the balance sheet.

Inputs used to determine estimated fair value of the common warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The estimates used to determine the fair value of these common warrants represent our best estimates, but may prove to be wrong. Therefore, the change in fair value of warrant liabilities could be materially different in the future.

Stock-Based Compensation

We account for all stock-based compensation granted to employees and non-employees using a fair value method. Stock-based compensation is measured at the grant date fair value and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. To the extent that actual forfeitures differ from our estimates, the differences are recorded as a cumulative adjustment in the period the estimates were adjusted. Stock-based compensation expense recognized in the consolidated financial statements is based on awards that ultimately vest.

The assumptions used in determining the fair value of stock-based awards represent our best estimates, but the estimates involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different in the future.

Smaller Reporting Company

We qualify as a “smaller reporting company” under the rules of the Securities Act and the Exchange Act. As a result, we may choose to take advantage of certain scaled disclosure requirements available specifically to smaller reporting companies. We will remain a smaller reporting company until the last day of the fiscal year in which the aggregate market value of our common stock held by non-affiliated persons and entities, or our public float, is more than $700 million as of the last business day of our most recently completed second fiscal quarter, or until the fiscal year following the year in which we have at least $100 million in revenue and at least $250 million in public float as of the last business day of our most recently completed second fiscal quarter.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company under the rules of the Securities Act and the Exchange Act and are not required to provide this information required under this item.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements together with the report of our independent registered public company accounting firm, required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those consolidated financial statements is found in Item 15.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), that are designed to ensure information required to be disclosed by us in reports we file or submit under the Exchange Act 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 principle financial officer, to allow timely decisions regarding required disclosure. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore, the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls. The design of any system of controls is also based in part upon certain assumptions about the

likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies and procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of controls, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our system of controls to enhance, where necessary, our control policies and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control over Financial Reporting

Our 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), to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Internal control over financial reporting includes our policies and procedures, such as our Code of Business Conduct and Ethics, which (i) require our employees, officers and directors to adhere to certain ethical standards; (ii) require the maintenance of records, in reasonable detail, to help to ensure that our transactions, assets and liabilities are accurately and fairly recorded; (iii) provide reasonable assurance that transactions are authorized by our management and directors and are recorded as necessary to allow for the accurate preparation of financial statements in accordance with U.S. GAAP; and (iv) provide reasonable assurance regarding the safeguarding of our assets and the prevention or timely detection of the unauthorized acquisition, use or disposition of our assets, which could have a material effect on the financial statements. Internal control over financial reporting includes the controls themselves, management's monitoring of those controls, actions taken to correct any deficiencies identified and oversight of our internal control environment by the Audit Committee of our Board of Directors. Any system of internal control has inherent limitations and therefore may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate over time because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of the end of our fiscal year 2025 and has reviewed the results of this assessment with the Audit Committee of our Board of Directors. Management based its assessment on criteria established in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the fiscal quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established for registrants that are non-accelerated filers.

Item 9B. Other Information

During the fiscal quarter ended December 31, 2025, no officer or director, as defined in Rule 16a-1(f) of the Exchange Act, informed us of the adoption, modification or termination of any "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K .

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 11. Executive Compensation

Incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

Incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

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

Incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

Item 14. Principal Accountant Fees and Services

Incorporated by reference from the information in our Proxy Statement for our 2026 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements

See the "Index to Consolidated Financial Statements" on page F-1 below for the list of financial statements filed as part of this report.

(a)(2) Financial Statement Schedules

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements filed as part of this Annual Report on Form 10-K or the notes thereto or is not required.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

		Incorporated by Reference			
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date
2.1*	Agreement and Plan of Merger, dated November 13, 2023, by and among Selecta Biosciences, Inc., Sakura Merger Sub I, Inc., Sakura Merger Sub II, LLC, and Cartesian Therapeutics, Inc.	8-K	001-37798	2.1	11/13/2023
3.1(a)	Restated Certificate of Incorporation of Selecta Biosciences, Inc.	8-K	001-37798	3.1	6/29/2016
3.1(b)	Certificate of Amendment to the Restated Certificate of Incorporation of Selecta Biosciences, Inc., dated June 21, 2022	8-K	001-37798	3.1	6/21/2022
3.1(c)	Certificate of Amendment to the Restated Certificate of Incorporation of Selecta Biosciences, Inc., dated November 13, 2023	8-K	001-37798	3.3	11/13/2023
3.1(d)	Certificate of Amendment to the Restated Certificate of Incorporation, as amended, of Cartesian Therapeutics, Inc., dated March 28, 2024.	8-K	001-37798	3.2	3/28/2024
3.2	Amended and Restated By-laws of Cartesian Therapeutics, Inc.	8-K	001-37798	3.2	10/30/2025
4.1	Specimen Stock Certificate evidencing the shares of common stock	10-K	001-37798	4.1	3/13/2025
4.2	Form of Warrant to Purchase Shares of Series E Preferred Stock, dated December 31, 2015, issued by the Registrant to Oxford Finance LLC and Square One Bank, together with a schedule of warrant holders	S-1	333-211555	4.6	5/24/2016
4.3	Registration Rights Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)	10-Q	001-37798	4.1	8/6/2020
4.4	Registration Rights Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ), as amended on November 4, 2020	10-Q	001-37798	4.2	11/5/2020
4.5	Form of Warrant to Purchase Stock, dated August 31, 2020, issued by Selecta Biosciences, Inc. to Oxford Finance LLC and Silicon Valley Bank, together with a schedule of warrants.	8-K	001-37798	4.1	9/3/2020
4.6	Form of Common Stock Purchase Warrant, dated April 11, 2022	8-K	001-37798	4.1	4/6/2022
4.7	Form of Contingent Value Rights Agreement	8-K	001-37798	2.1	11/13/2023
4.8	Registration Rights Agreement, by and among Selecta Biosciences, Inc. and certain purchasers party thereto	8-K	001-37798	10.2	11/13/2023
4.9(a)	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock	8-K	001-37798	3.4	11/13/2023

4.9(b)	Certificate of Amendment to the Certificate of Designation of Series A Non-Voting Convertible Preferred Stock, dated March 26, 2024.	8-K	001-37798	3.1	3/28/2024
4.10	Certificate of Designation of Preferences, Rights and Limitations of Series B Non-Voting Convertible Preferred Stock	8-K	001-37798	3.1	7/2/2024
4.11	Form of Registration Rights Agreement, dated as of July 2, 2024, by and among the Registrant and the Investors named therein.	8-K	001-37798	10.2	7/2/2024
4.12	Description of Securities	—	—	—	Filed herewith
10.1#	Amended and Restated 2016 Incentive Award Plan and form of award agreements thereunder	S-1	333-281204	10.1	8/2/2024
10.2#	2016 Employee Stock Purchase Plan	S-1/A	333-211555	10.3	6/8/2016
10.3#	Amended and Restated Cartesian Therapeutics, Inc. 2018 Employment Inducement Incentive Award Plan, and forms of award agreements thereunder	10-K	001-37798	10.3	3/13/2025
10.4#	Cartesian Therapeutics, Inc. 2016 Stock Incentive Plan, and forms of award agreements thereunder	S-8	333-276486	99.1	1/12/2024
10.5#	Non-Employee Director Compensation Program	10-K	001-37798	10.5	3/13/2025
10.6#	Form of Indemnification Agreement for Directors and Officers	S-1	333-211555	10.5	5/24/2016
10.7†	Amended and Restated License Agreement, dated as of May 31, 2017, by and between the Registrant and Shenyang Sunshine Pharmaceutical Co., Ltd.	10-Q	001-37798	10.6	8/11/2017
10.8†	Manufacturing Services Agreement, dated as of August 1, 2014, by and between the Registrant and Shenyang Sunshine Pharmaceutical Co., Ltd.	S-1	333-211555	10.10	5/24/2016
10.9(a)	Lease Agreement by and between BRE-BMR Grove LLC and Selecta Biosciences, Inc. dated July 23, 2019	10-Q	001-37798	10.3	11/8/2019
10.9(b)	First Amendment to Lease by and between BRE-BMR Grove LLC and Selecta Biosciences, Inc. dated September 1, 2022	10-Q	001-37798	10.1	11/3/2022
10.10(a)†	Lease Agreement by and between 704 Quince Orchard Owner, LLC and Cartesian Therapeutics, Inc. dated May 11, 2018	10-K	001-37798	10.11(a)	3/7/2024
10.10(b)†	First Amendment to Lease Agreement by and between 704 Quince Orchard Owner, LLC and Cartesian Therapeutics, Inc. dated March 22, 2021	10-K	001-37798	10.11(b)	3/7/2024
10.10(c)†	Second Amendment to Lease Agreement by and between 704 Quince Orchard Owner, LLC and Cartesian Therapeutics, Inc. dated May 3, 2021	10-K	001-37798	10.11(c)	3/7/2024
10.11(a)†	Lease Agreement by and between 7495 RP, LLC and Cartesian Therapeutics, Inc. dated February 28, 2024	10-K	001-37798	10.12	3/7/2024
10.11(b)†	First Amendment to Lease Agreement by and between 7495 RP, LLC and the Registrant dated May 7, 2024	10-Q	001-37798	10.3(b)	5/8/2024
10.11(c)†	Second Amendment to Lease Agreement by and between 7495 RP, LLC and the Registrant dated August 30, 2024	10-Q	001-37798	10.1	11/7/2024
10.11(d)†	Third Amendment to Lease Agreement by and between 7495 RP, LLC and the Registrant dated March 13, 2025	10-Q	001-37798	10.1	5/8/2025
10.11(e)	Fourth Amendment to Lease Agreement by and between 7495 RP, LLC and the Registrant dated June 26, 2025	10-Q	001-37798	10.1	8/7/2025
10.12#	Employment Agreement, dated as of September 25, 2018, by and between the Registrant and Carsten Brunn, Ph.D.	8-K	001-37798	10.2	9/27/2018
10.13#	Employment Agreement, dated as of November 9, 2022, by and between the Registrant and Blaine Davis	10-K	001-37798	10.15	3/2/2023
10.14#	Employment Agreement, dates as of March 26, 2024, by and between the Registrant and Christopher Jewell, Ph.D.	8-K	001-37798	10.1	4/1/2024
10.15#	Employment Agreement, dates as of March 28, 2024, by and between the Registrant and Metin Kurtoglu, M.D., Ph.D.	8-K	001-37798	10.2	4/1/2024

10.16(a)†	License and Development Agreement, dated as of June 11, 2020, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)	10-Q	001-37798	10.2	8/6/2020
10.16(b)†	Amendment No. 1 to License and Development Agreement, dated as of October 31, 2023, by and between the Registrant and Swedish Orphan Biovitrum AB (Publ)	10-K	001-37798	10.15(b)	3/7/2024
10.17†	Patent License Agreement, between Cartesian Therapeutics, Inc. and the U.S. Department of Health and Human Services, as represented by the National Cancer Institute of the National Institutes of Health, dated September 16, 2019	10-K	001-37798	10.16	3/7/2024
10.18†	Patent License Agreement by and between Biogen MA, Inc. and Cartesian Therapeutics, Inc., dated September 8, 2023	10-K	001-37798	10.17	3/7/2024
10.19#	Form of Retention Bonus Letter	8-K	001-37798	10.3	11/13/2023
10.20	Securities Purchase Agreement, dated as of November 13, 2023, by and among Selecta Biosciences, Inc. and each purchaser identified on Annex A thereto	8-K	001-37798	10.1	11/13/2023
10.21	Sales Agreement, dated as of December 13, 2024, by and between the Registrant and Leerink Partners LLC	S-3	333-283803	1.2	12/13/2024
10.22#	Separation Agreement, dated as of October 20, 2025, by and between the Company and Christopher Jewell	—	—	—	Filed herewith
10.23#†	Separation Agreement, dated as of April 29, 2025, by and between the Company and Metin Kurtoglu	10-Q	001-37798	10.2	5/8/2025
19.1	Cartesian Therapeutics, Inc. Insider Trading Policy	—	—	—	Filed herewith
21.1	Subsidiaries of Cartesian Therapeutics, Inc.	—	—	—	Filed herewith
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm	—	—	—	Filed herewith
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
97	Cartesian Therapeutics, Inc. Compensation Clawback Policy	10-K	001-37798	97	3/7/2024
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	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	—	—	—	Filed herewith

# Indicates management contract or compensatory plan.

* Certain annexes, schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted attachment to the SEC on a confidential basis upon request.

† Certain confidential information contained in this exhibit, marked by brackets and asterisks, has been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because the information (i) is not material and (ii) is the type of information that the Company both customarily and actually treats as private and confidential.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

CARTESIAN THERAPEUTICS, INC.

Date: March 9, 2026

By: /s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President, Chief Executive Officer and Chairman of the Board

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

Signature	Title	Date
/s/ Carsten Brunn, Ph.D. Carsten Brunn, Ph.D.	President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 9, 2026
/s/ Blaine Davis Blaine Davis	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2026
/s/ Patrick Zenner Patrick Zenner	Lead Independent Director	March 9, 2026
/s/ Timothy C. Barabe Timothy C. Barabe	Director	March 9, 2026
/s/ Adrian Bot Adrian Bot	Director	March 9, 2026
/s/ Nishan de Silva, M.D. Nishan de Silva, M.D.	Director	March 9, 2026
/s/ Murat Kalayoglu, M.D., Ph.D. Murat Kalayoglu, M.D., Ph.D.	Director	March 9, 2026
/s/ Kemal Malik MBBS Kemal Malik, MBBS	Director	March 9, 2026
/s/ Michael Singer, M.D., Ph.D. Michael Singer, M.D., Ph.D.	Director	March 9, 2026
/s/ Timothy Springer, Ph.D. Timothy Springer, Ph.D.	Director	March 9, 2026

Cartesian Therapeutics, Inc. and Subsidiaries

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Cartesian Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cartesian Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in convertible preferred stock and stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as

a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of contingent value right

Description of the Matter

As of December 31, 2025, the Company recorded the contingent value right liability and the contingent value right liability, net of current portion of zero and $392.1 million, respectively. As described in Note 2, the Company estimates the fair value of the Contingent Value Right ("CVR") using a Monte Carlo simulation to estimate future cash flows associated with the legacy assets, including the expected milestone and royalty payments under the Company's License and Development Agreement with Swedish Orphan Biovitrum AB (publ.) as amended, net of deductions. Changes in the fair value of the liability are presented in the consolidated statements of operations and comprehensive loss. The liability value is calculated based on significant inputs that are not observable in the market such as estimated cash flows, estimated probabilities of success, and expected volatilities of revenues, which represent Level 3 measurements within the fair value hierarchy. For the year ended December 31, 2025, the Company recorded a loss on the change in the fair value of the contingent value right liability of $4.4 million.

Auditing the fair value of the CVR liability was complex due to the significant judgment required in estimating the fair value. In particular, the fair value estimate required the use of valuation methodologies that were sensitive to significant assumptions including expected milestone and royalty payments and discount rate which are based on estimates of future market or economic conditions.

How We Addressed the Matter in Our Audit

To test the fair value of the CVR liability, our audit procedures included, among others, assessing the appropriateness of the valuation methodology and testing the significant assumptions and the completeness and accuracy of the underlying data used by the Company. We compared the assumptions for expected milestone and royalty payments to projected industry revenue growth rates and other factors considered by management in developing the model. We involved our valuation specialist to assist in evaluating the valuation methodologies and discount rate used to value the CVR liability.

Impairment of Goodwill and Indefinite-Lived Intangibles

Description of the Matter

As of December 31, 2025, the Company's goodwill and indefinite-lived intangible asset balances were $48.2 million and $93.9 million, respectively. As disclosed in Note 2 of the consolidated financial statements, goodwill and indefinite-lived intangible assets are tested for impairment annually, or more frequently if events or circumstances indicate the fair value of the reporting unit or the intangible assets may be below its carrying value. In order to determine if assets have been impaired, assets are tested at the lowest level for which identifiable independent cash flows are available. An impairment loss is recognized when the sum of projected discounted cash flows is less than the carrying value of the asset group. If the carrying value exceeds the fair value, an impairment charge is recognized equal to the difference between the carrying value of the reporting unit and its fair value for goodwill, or the difference between the carrying value of the indefinite-lived intangible assets and its fair value for indefinite-lived intangible assets. During the year ended December 31, 2025, the Company recorded an impairment charge related to the Descartes-08 for SLE indefinite-lived intangible asset of $56.7 million.

Auditing management's impairment tests of goodwill and indefinite-lived intangible assets was complex and judgmental due to the measurement uncertainty in determining the fair values of the reporting unit and indefinite-lived intangible assets. In particular, the fair value estimates of the reporting unit and indefinite-lived intangible assets were sensitive to changes in significant assumptions such as certain assumptions that form the basis of the forecasted results (e.g., revenue, discount rates, control premiums and probability of clinical success). These significant assumptions are especially challenging to audit as they are forward-looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit	To test the estimated fair values of the reporting unit and indefinite-lived intangible assets, our audit procedures included, among others, evaluating the Company's valuation methodology and significant assumptions used by management, and testing the completeness and accuracy of the underlying data supporting the significant assumptions mentioned above. We performed sensitivity analyses of significant assumptions to evaluate the changes in the fair value of the reporting unit and indefinite-lived intangible assets resulting from changes in the assumptions. We compared the significant assumptions used by management to current industry and economic trends. We utilized internal valuation specialists to assist in our evaluation of the Company's valuation methodologies and certain significant assumptions. In addition, for goodwill we also tested management's reconciliation of the fair value of the reporting unit to the market capitalization of the Company.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2009.

Boston, Massachusetts

March 9, 2026

Cartesian Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
(Amounts in thousands, except share data and par value)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 125,139	$ 212,610
Accounts receivable	1,115	872
Prepaid expenses and other current assets	3,022	3,144
Total current assets	129,276	216,626
Property and equipment, net	12,185	9,912
Right-of-use assets, net	5,601	5,535
In-process research and development assets	93,900	150,600
Goodwill	48,163	48,163
Long-term restricted cash	1,735	1,669
Investment	—	2,000
Long-term prepaid expenses and other assets	5,551	518
Total assets	$ 296,411	$ 435,023
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,288	$ 288
Accrued expenses and other current liabilities	9,498	12,076
Lease liabilities	4,151	2,851
Contingent value right liability	—	7,761
Total current liabilities	14,937	22,976
Lease liabilities, net of current portion	8,525	11,133
Warrant liability	141	3,836
Contingent value right liability, net of current portion	392,100	387,739
Deferred tax liabilities, net	6,948	16,141
Total liabilities	422,651	441,825
Commitments and contingencies (Note 18)		
Stockholders' deficit:		
Series A Preferred Stock, $0.0001 par value; 134,904.563 shares authorized as of December 31, 2025 and 2024; 120,790.402 shares issued and outstanding as of December 31, 2025 and 2024	—	—
Series B Preferred Stock, $0.0001 par value; 437,927 shares authorized, issued and outstanding as of December 31, 2025 and 2024	—	—
Preferred stock, $0.0001 par value; 9,427,168.437 shares authorized as of December 31, 2025 and 2024; no shares issued and outstanding as of December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized as of December 31, 2025 and 2024; 26,011,106 and 25,767,369 shares issued and outstanding as of December 31, 2025 and 2024, respectively	3	3
Additional paid-in capital	700,706	689,887
Accumulated deficit	(822,373)	(692,071)
Accumulated other comprehensive loss	(4,576)	(4,621)
Total stockholders' deficit	(126,240)	(6,802)
Total liabilities and stockholders' deficit	$ 296,411	$ 435,023

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

Cartesian Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Loss
(Amounts in thousands, except share and per share data)

	Year Ended December 31,	
	2025	**2024**
Revenues:		
Collaboration and license	$ 400	$ 38,275
Grant	2,397	638
Total revenues	2,797	38,913
Operating expenses:		
Research and development	58,034	45,105
General and administrative	31,468	30,126
Impairment of indefinite-lived intangible and long-lived assets	56,700	7,579
Total operating expenses	146,202	82,810
Operating loss	(143,405)	(43,897)
Other income (expense):		
Interest income	6,579	7,386
Gain on change in fair value of warrant liabilities	3,695	2,558
Loss on change in fair value of contingent value right liability	(4,354)	(36,900)
Loss on change in fair value of forward contract liabilities	—	(6,890)
Other (expense) income, net	(2,010)	606
Total other income (expense), net	3,910	(33,240)
Loss before income taxes	(139,495)	(77,137)
Income tax benefit (expense)	9,193	(287)
Net loss	$ (130,302)	$ (77,424)
Other comprehensive income (loss):		
Foreign currency translation adjustment	45	(21)
Total comprehensive loss	$ (130,257)	$ (77,445)
Net loss	$ (130,302)	$ (77,424)
Net loss per share allocable to common stockholders:		
Basic	$ (5.02)	$ (4.48)
Diluted	$ (5.02)	$ (4.49)
Weighted-average common shares outstanding:		
Basic	25,973,329	17,276,822
Diluted	25,973,329	17,357,943

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

Cartesian Therapeutics, Inc. and Subsidiaries

Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit

(Amounts in thousands, except share data)

	Series A Preferred Stock		Options for Series A Preferred Stock	Series A Preferred Stock		Series B Preferred Stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Stockholders' deficit
	Shares	Amount	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	435,120.513	$296,851	$ 3,703	—	$ —	—	$ —	5,397,597	$ 1	$ 179,062	$ (614,647)	$ (4,600)	$ (440,184)
Issuance of Series A Preferred Stock in connection with private placement and settlement of related forward contract	99,140.326	75,197	—	—	—	—	—	—	—	—	—	—	—
Transfer of Series A Preferred Stock and options for Series A Preferred Stock to permanent equity	(534,260.839)	(372,048)	(3,703)	534,260.839	—	—	—	—	—	375,751	—	—	375,751
Conversion of Series A Preferred Stock to common stock	—	—	—	(413,470.437)	—	—	—	13,782,324	2	(2)	—	—	—
Issuance of Series B Preferred Stock and common stock in connection with private placement, net of issuance costs of $5,585	—	—	—	—	—	2,937,903	—	3,563,247	—	124,438	—	—	124,438
Conversion of Series B Preferred Stock to common stock	—	—	—	—	—	(2,499,976)	—	2,499,976	—	—	—	—	—
Issuance of common stock upon exercise of options	—	—	—	—	—	—	—	458,544		1,179	—	—	1,179
Issuance of common stock upon exercise of warrants	—	—	—	—	—	—	—	65,681		2,877	—	—	2,877
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	6,582	—	—	6,582
Currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	(21)	(21)
Net loss	—	—	—	—	—	—	—	—	—	—	(77,424)	—	(77,424)
Balance at December 31, 2024	—	$ —	$ —	120,790.402	$ —	437,927	$ —	25,767,369	$ 3	$ 689,887	$ (692,071)	$ (4,621)	$ (6,802)
Issuance of common stock upon exercise of options	—	—	—	—	—	—	—	90,444	—	298	—	—	298
Issuance of common stock upon vesting of restricted stock units	—	—	—	—	—	—	—	153,293	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	10,521	—	—	10,521
Currency translation adjustment	—	—	—	—	—	—	—	—	—	—	—	45	45
Net loss	—	—	—	—	—	—	—	—	—	—	(130,302)	—	(130,302)
Balance at December 31, 2025	—	$ —	$ —	120,790.402	$ —	437,927	$ —	26,011,106	$ 3	$ 700,706	$ (822,373)	$ (4,576)	$ (126,240)

On April 4, 2024, the Company effected a 1-for-30 reverse split of its issued and outstanding shares of common stock, or the Reverse Stock Split. As a result of the Reverse Stock Split, all figures in this Annual Report on Form 10-K relating to shares of the Company's common stock (such as share amounts, per share amounts, and conversion rates and prices), including but not limited to, the consolidated financial statements and footnotes included herein, have been adjusted to reflect the Reverse Stock Split for all periods presented.

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

Cartesian Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(Amounts in thousands)

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (130,302)	$ (77,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,959	1,151
Non-cash lease expense	778	2,437
Loss on disposal of property and equipment	—	273
Impairment of indefinite-lived intangible and long-lived assets	56,700	7,579
Stock-based compensation expense	10,521	6,582
Gain on change in fair value of warrant liabilities	(3,695)	(2,558)
Loss on change in fair value of CVR liability	4,354	36,900
Loss on change in fair value of forward contract liabilities	—	6,890
Loss on impairment of investment	2,000	—
(Benefit) provision for deferred taxes	(9,193)	287
Changes in operating assets and liabilities:		
Accounts receivable	(243)	4,998
Unbilled receivable	—	2,981
Prepaid expenses and other assets	(5,298)	1,747
Accounts payable	1,066	(2,927)
Deferred revenue	—	(5,849)
Accrued expenses and other liabilities	(3,588)	(6,741)
Net cash used in operating activities	(73,941)	(23,674)
Cash flows from investing activities		
Purchases of property and equipment	(5,454)	(9,093)
Proceeds from the sale of property and equipment	—	351
Net cash used in investing activities	(5,454)	(8,742)
Cash flows from financing activities		
Proceeds from issuance of Series A Preferred Stock, gross in private placement	—	40,000
Net proceeds from issuance of common stock and Series B Preferred Stock in private placement	—	124,438
Equity offering costs	(624)	(66)
Proceeds from exercise of common warrants	—	2,877
Proceeds from exercise of stock options	323	1,179
Distribution of Contingent Value Rights	(7,754)	—
Net cash (used in) provided by financing activities	(8,055)	168,428
Effect of exchange rate changes on cash	45	(21)
Net change in cash, cash equivalents, and restricted cash	(87,405)	135,991
Cash and cash equivalents at beginning of period	214,279	78,288
Cash and cash equivalents at end of period	$ 126,874	$ 214,279
Non-cash investing and financing activities		
Purchase of property and equipment not yet paid	$ 18	$ 847
Equity offering costs in accrued liabilities	$ 30	$ 451
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ 844	$ 5,246

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

Cartesian Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

1. Description of the Business

Cartesian Therapeutics, Inc., or the Company, (formerly known as Selecta Biosciences, Inc., or Selecta) was incorporated in Delaware on December 10, 2007, and is headquartered in Frederick, Maryland. The Company is a late clinical-stage biotechnology company pioneering cell therapy for the treatment of autoimmune diseases. The Company leverages its proprietary technology and manufacturing platform to introduce mRNA into cells to provide a therapeutic effect to patient suffering from a variety of autoimmune conditions. Unlike DNA, mRNA degrades naturally over time without integrating into the cell's genetic material. Its cell therapies are designed to be dosed repeatedly like conventional drugs, administered in an outpatient setting and given without pre-treatment chemotherapy, which is required with many conventional cell therapies.

On November 13, 2023, the Company acquired, in accordance with the terms of the Agreement and Plan of Merger, or the Merger Agreement, the assets of the Delaware corporation which, immediately prior to the Merger (as defined below), was known as Cartesian Therapeutics, Inc., or Old Cartesian. The transaction was structured as a stock-for-stock transaction pursuant to which all of Old Cartesian's outstanding shares of capital stock were exchanged based on a fixed exchange ratio for consideration of 224,099 shares of common stock, par value $0.0001 per share, of the Company, or the common stock, and 384,930.724 shares of the newly designated Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, or the Series A Preferred Stock, or the Merger. The Series A Preferred Stock is intended to have economic rights similar to the common stock, but with only limited voting rights. Additionally, the Company assumed all outstanding stock options of Old Cartesian. The common stock and Series A Preferred Stock related to the Merger were issued on December 5, 2023.

The Company's Product Candidates

The Company aims to provide a personalized approach to treating patients that begins with the collection of a patient's cells which is then used to manufacture the Company's cell therapy product candidates. Once a patient's cells have expanded in the Company's process, mRNA is introduced to deliver a chimeric antigen receptor into the cell. Once the manufacturing process is complete, the product is sent back to the treating physician where they administer six weekly infusions of the Company's cell therapy candidate to the patient. The Company's product candidate is specifically designed to target and destroy the pathogenic, self-reactive cell that are the underlying cause of the autoimmune disease, with the goal of creating a precision immune reset for the patient.

Descartes-08, the Company's lead cell therapy product candidate, is an autologous chimeric antigen receptor T-cell therapy, or CAR-T, product targeting B-cell maturation antigen, or BCMA, in clinical development for the treatment of generalized myasthenia gravis, or MG, and myositis, specifically, moderate to sever multi-refractory dermatomyositis and anti antisynthetase syndrome. In contrast to conventional DNA-based CAR T-cell therapies, the Company's CAR-T administration is designed to not require preconditioning chemotherapy, to be administered in the outpatient setting and does not carry the risk of genomic integration associated with cancerous transformation. Descartes-08 has been granted Orphan Drug Designation and Regenerative Medicine Advanced Therapy Designation by the U.S. Food and Drug Administration, or FDA, for the treatment of MG, and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis.

Liquidity and Management's Plan

As of December 31, 2025, the Company had an accumulated deficit of $822.4 million. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research and development of its product candidates and its administrative organization.

As of December 31, 2025, the Company's cash, cash equivalents, and restricted cash were $126.9 million, of which $1.7 million was restricted cash related to lease commitments. The Company believes the cash, cash equivalents and restricted cash as of December 31, 2025 will enable it to fund its current planned operations for at least the next 12 months from the date of issuance of these financial statements, though it may pursue additional cash resources through public or private equity or debt financings or by establishing collaborations with other companies. However, there is no guarantee that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. Further, the liability associated with the Contingent Value Rights, or CVR, Agreement (as defined below) will be settled solely through cash flow received under the Company's License and Development Agreement, or as so amended, the Sobi License, with Swedish Orphan Biovitrum AB (publ.), or Sobi, and any other Gross Proceeds (as defined in the CVR Agreement) net of certain agreed deductions. Under the CVR Agreement, 100% of all milestone payments, royalties and other amounts paid to the Company or controlled entities under the Sobi License, and any other Gross Proceeds will be distributed, net of specified deductions, to holders of the CVRs. There is no obligation to the Company to fund any amount related to the CVR liability. See Note 6, "Fair Value Measurements".

If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand its operations or otherwise capitalize on its commercialization of its product candidates.

2. Summary of Significant Accounting Policies

Basis of presentation and consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Selecta (RUS), LLC, or Selecta (RUS), a Russian limited liability corporation, Selecta Biosciences Security Corporation, a Massachusetts securities corporation which the Company dissolved in December 2024, and Cartesian Bio, LLC, a Delaware limited liability company, which is a variable interest entity for which the Company is the primary beneficiary and have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification, or ASC and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB. All significant intercompany accounts and transactions have been eliminated.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's management considers many factors in selecting appropriate financial accounting policies and controls, and bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. In preparing these consolidated financial statements, management used significant estimates in the following areas, among others: estimated fair value of the intangible assets acquired in connection with the Merger, estimated fair value of the CVRs, deferred income taxes, revenue recognition, estimated accrued research and development expenses, stock-based compensation expense, estimated fair value of the liability-classified warrants, and impairment of goodwill, indefinite-lived intangible assets and long-lived assets. The Company assesses the above estimates on an ongoing basis; however, actual results could materially differ from those estimates.

Segment information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision maker, or the CODM, for the purposes of assessing performance and allocating resources. The Company views its operations and manages its business in one operating segment, which prior to the Merger related to the research and development of nanoparticle immunomodulatory drugs for the treatment and prevention of human diseases and subsequent to the Merger relates to the research and development of cell therapy product candidates. The Company's CODM function is fulfilled by its Chief Executive Officer. The CODM function assesses performance for the segment and decides how to allocate resources based on consolidated net loss that is also reported on the consolidated statements of operations and comprehensive loss. The CODM function uses net loss to monitor budget versus actual results to assess performance of the segment. Segment assets are the same as total assets on the Company's consolidated balance sheets. All long-lived assets are located in the United States. Long-lived assets consist of property and equipment, net, and operating lease right-of-use assets.

Cash Equivalents, Marketable Securities and Investments

Cash equivalents include all highly liquid investments maturing within 90 days from the date of purchase. Marketable securities consist of securities with remaining maturities greater than 90 days when purchased. The Company classifies these marketable securities as available-for-sale and records them at fair value in the accompanying consolidated balance sheets. Marketable securities with less than one year until maturity are classified as short term, while marketable securities with maturities greater than one year are classified as long term. Unrealized gains or losses are included in accumulated other comprehensive loss. Premiums or discounts from par value are amortized to interest income over the life of the underlying investment. Although available to be sold to meet operating needs or otherwise, securities are generally held through maturity. The cost of securities sold is determined based on the specific identification method for purposes of recording realized gains and losses.

The Company has also in the past invested in equity securities of a company whose securities are not publicly traded and where fair value is not readily available. This investment is recorded using cost minus impairment adjusted for changes in observable prices, depending on our ownership percentage and other factors that suggest the Company has a significant influence. The Company monitors this investment to evaluate whether any increase or decline in its value has occurred, based

on the implied value of recent company financings, public market prices of comparable companies and general market conditions. This investment is included in investments in the consolidated balance sheets.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, short-term deposits, investments, accounts receivable, and unbilled receivables. Cash and cash equivalents are deposited with federally insured financial institutions in the United States and may, at times, exceed federally insured limits. Management believes that the financial institutions that hold the Company's deposits are financially creditworthy and, accordingly, minimal risk exists with respect to those balances.

Fair Value of Financial Instruments

The Company's financial instruments consist mainly of cash equivalents, restricted cash, accounts receivable, accounts payable, accrued expenses and other current liabilities, investments, warrants to purchase common stock, forward contract liabilities, and contingent value rights. The carrying amounts of cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued expenses and other current liabilities approximate their estimated fair value due to their short-term maturities.

Accounting standards define fair value 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 three-level hierarchy is used to prioritize 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 measurements), and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1—Level 1 inputs are quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2—Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term of the asset or liability.

Level 3—Level 3 inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

To the extent that a 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. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The fair value of warrant liabilities and contingent value rights are determined using Level 3 inputs.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, the Company's own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. The Company uses prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may change for many instruments. This condition could cause an instrument to be reclassified within levels in the fair value hierarchy.

The carrying amounts reflected in the consolidated balance sheet for investments approximate fair value and are assessed for impairment quarterly.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, generally seven years for furniture and fixtures, five years for laboratory equipment, software and office equipment and three years for computer equipment. Leasehold improvements are amortized over their useful life or the life of the lease, whichever is shorter. Major additions and betterments are capitalized. Maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to operations as incurred. Costs incurred for construction in progress are recorded as assets and are not amortized until the construction is substantially complete and the assets are ready for their intended use.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In order to determine if assets have been impaired, assets are tested at the lowest level for which identifiable independent cash flows are available. An impairment loss is recognized when the sum of projected undiscounted cash flows is less than the carrying value of the asset group. The measurement of the impairment loss to be recognized is based on the difference between the fair value and the carrying value of the asset group. The Company did not recognize an impairment charge on its long-lived assets during the year ended December 31, 2025. The Company recognized an impairment charge on its right of use assets and related furniture and fixtures during the year ended December 31, 2024.

Accumulated Other Comprehensive Loss

Comprehensive loss is defined as the change in the equity of a business entity during a period from transactions and other events and circumstances from non-owner sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners. Comprehensive loss consists of: (i) all components of net loss and (ii) all components of comprehensive loss other than net loss, referred to as other comprehensive loss. Other comprehensive loss is comprised of foreign currency translation adjustments.

Collaboration and License Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. Pursuant to ASC Topic 606, Revenue from Contracts with Customers (ASC 606), a customer is a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract, including whether they are distinct in the context of the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. If a promised good or service is not distinct, it is combined with other promised goods or services into a performance obligation. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Collaboration and License Revenue

The Company currently generates its revenue through collaboration and license agreements with strategic collaborators for the development and commercialization of product candidates. Collaboration and license agreements with customers are generally accounted for in accordance with ASC 606. The Company analyzes collaboration arrangements by first assessing whether they are within the scope of ASC Topic 808, Collaborative Arrangements (ASC 808), and evaluates 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 that are dependent on the commercial success of such activities. Collaboration agreements with customers that are not within the scope of ASC 808 are accounted for in accordance with ASC 606. To the extent the collaboration agreement is within the scope of ASC 808, the Company also assesses whether any aspects of the agreement are within the scope of other accounting literature (specifically ASC 606). If the Company concludes that some or all aspects of the agreement are distinct and represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC 606. The Company recognizes the shared costs incurred that are not within the scope of other accounting literature as a component of the related expense in the period incurred by analogy to ASC Topic 730, Research and Development (ASC 730), and records reimbursements from counterparties as an offset to the related research and development costs. In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under the agreements in accordance with ASC 606, the Company performs the five steps above. As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

The terms of the Company's arrangements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; (iii) royalties on net sales of licensed products; (iv) reimbursements or cost-sharing of research and development expenses; and (v) profit/loss sharing arising from co-promotion arrangements.

Licenses of Intellectual Property

If the license to the Company's intellectual property is determined to be distinct from the other promised goods and services identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If not distinct, the license is combined with other promised goods and services in the contract. For licenses that are combined with other promised goods and services, the Company assesses the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. Optional licenses are evaluated to determine if they are issued at a discount, and therefore, represent material rights and accounted for as separate performance obligations.

Milestone Payments

At the inception of each arrangement that includes developmental and regulatory milestone payments, the Company evaluates whether the achievement of each milestone specifically relates to the Company's efforts to satisfy a performance obligation or transfer a distinct good or service within a performance obligation. If the achievement of a milestone is considered a direct result of the Company's efforts to satisfy a performance obligation or transfer a distinct good or service and the receipt of the payment is based upon the achievement of the milestone, the associated milestone value is allocated to that distinct good or service. If the milestone payment is not specifically related to the Company's effort to satisfy a performance obligation or transfer a distinct good or service, the amount is allocated to all performance obligations using the relative standalone selling price method. The Company also evaluates the milestone to determine whether they are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price to be allocated, otherwise, such amounts are constrained and excluded from the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the transaction price. Any such adjustments to the transaction price are allocated to the performance obligations on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation shall be recognized as revenue, or as a reduction of revenue, in the period in which the transaction price changes.

Manufacturing Supply Services

Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the customer's discretion are evaluated to determine if they are distinct and optional. For optional services that are distinct, the Company assesses if they are priced at a discount, and therefore, provide a material right to the licensee to be accounted for as separate performance obligations.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied) in accordance with the royalty recognition constraint.

Grant Revenue

The Company has contracts with government-sponsored organizations for research and development related activities that provide for payments for reimbursable costs. The Company recognizes grant revenue from these contracts as it performs services under these arrangements when the funding is committed. Expenses associated with these contracts are recognized when incurred as research and development expense. Grant revenue and related expenses are presented gross in the consolidated statements of operations and comprehensive loss as the Company has determined it is the primary obligor under the arrangements relative to the research and development services it performs as lead technical expert. Amounts incurred that are subject to reimbursement from the sponsor are recorded as accounts receivable on the consolidated balance sheets.

Research and Development Costs

Costs incurred in the research and development of the Company's products are expensed as incurred. Research and development expenses include costs incurred in performing research and development activities, including salaries and benefits, stock-based compensation expenses, facilities cost, overhead costs, contract services, supplies and other outside costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Clinical Trial Costs

Clinical trial expenses are a significant component of research and development expenses, and the Company outsources a significant portion of these costs to third-parties. Third-party clinical trial expenses include patient costs, clinical research organization costs and costs for data management. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as a prepaid asset or accrued clinical trial cost. These third-party agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. Non-refundable advance clinical payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. The Company also records accruals for estimated ongoing clinical research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical clinical accrual estimates made by the Company have not been materially different from the actual costs.

Income Taxes

The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more-likely-than-not be realized.

The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more-likely-than-not that a position will be sustained, none of the benefit attributable to the position is recognized. The tax benefit to be recognized for any tax position that meets the more-likely-than-not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date, the Company has not incurred interest and penalties related to uncertain tax positions.

Warrants

The Company determines the accounting classification of warrants that are issued, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, and then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If warrants do not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable U.S. GAAP. After all relevant assessments are made, the Company concludes whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded in the statements of operations as a gain or loss. Equity classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Stock-Based Compensation

The Company accounts for all stock-based compensation granted to employees and non-employees using a fair value method. Stock-based compensation is measured at the grant date fair value and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. To the extent that actual forfeitures differ from the Company's estimates, the differences are recorded as a cumulative adjustment in the period the estimates were adjusted. Stock-based compensation expense recognized in the consolidated financial statements is based on awards that ultimately vest.

Net Income (Loss) Per Share

The Company applies the two-class method to compute basic and diluted net income (loss) per share attributable to common stockholders when it has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income (loss) for the period had been distributed. The Company's Series A Preferred Stock, Series B Preferred Stock and 2022 Warrants, as defined below, participate in any dividends declared by the Company and are therefore considered to be participating securities. The participating securities are not required to participate in the losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) per share attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potentially dilutive common shares. For purposes of this calculation, outstanding options to purchase common stock and Series A Preferred Stock, forward contracts to issue Series A Preferred Stock, restricted stock units, warrants to purchase common stock, contingently issuable shares, Series A Preferred Stock, and Series B Preferred Stock are considered potential dilutive common shares.

Contingent Liabilities

The Company accounts for its contingent liabilities in accordance with ASC Topic 450, Contingencies (ASC 450). A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter.

Leases

The Company accounts for its leases in accordance with ASC Topic 842, Leases (ASC 842), and determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company elected not to recognize leases with an original term less than one year on its balance sheet. Operating lease right-of-use assets and their corresponding lease liabilities are recorded based on the present value of lease payments over the expected remaining lease term. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, the fixed and in-substance fixed contract consideration must be allocated to lease and non-lease components based on their relative fair values. Non-components of a contract (e.g., administrative tasks that do not transfer a good or service to the Company, reimbursement or payment of a lessor's cost, etc.) do not receive an allocation of the consideration in the contract. Although allocation of consideration of lease and non-lease components is required, the Company elected the practical expedient to not separate lease components (e.g. land, building, etc.) and non-lease components (e.g., common area maintenance, consumables, etc.). The lease component results in an operating right-of-use asset being recorded on the balance sheet and amortized on a straight-line basis as lease expense. Right-of-use assets and operating lease liabilities are remeasured upon certain modifications to leases using the present value of remaining lease payments and the estimated incremental borrowing rate upon lease modification.

The Company enters into lease agreements with terms generally ranging from two to eight years. Some of the Company's lease agreements include Company options to either extend and/or early terminate the lease, the costs of which are included in its operating lease liabilities to the extent that such options are reasonably certain of being exercised. Leases with renewal options allow the Company to extend the lease term typically between one and five years. When determining the lease term, renewal options reasonably certain of being exercised are included in the lease term. When determining if a renewal option is reasonably certain of being exercised, the Company considers several economic factors, including but not limited to, the significance of leasehold improvements incurred on the property, whether the asset is difficult to replace, underlying contractual obligations, or specific characteristics unique to that particular lease that would make it reasonably certain that the Company would exercise such option. Renewal and termination options were generally not included in the lease term for the Company's existing operating leases. Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business. If determined to be a business combination, the Company accounts for the transaction under the acquisition method of accounting which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquiree and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations based on the fair value estimates as of the date of acquisition. In accordance with ASC Topic 805, Business Combinations (ASC 805) the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

Goodwill

Goodwill represents the amount of consideration paid in excess of the fair value of the identified net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing at a reporting unit level on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired. An entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Such qualitative factors include macroeconomic conditions, industry and market considerations, cost factors, overall financial performance and other relevant events. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount.

The Company evaluates goodwill for impairment at least annually on October 1, or the Assessment Date, and whenever facts and circumstances indicate that their carrying amounts may not be recoverable. For the years ended December 31, 2025 and 2024, the Company determined that there was no impairment to goodwill.

Indefinite-Lived Intangible Assets

Indefinite-lived intangible assets consist of in-process research and development, or IPR&D. The fair values of IPR&D assets acquired in business combinations are capitalized. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. The Company considers many factors in evaluating whether the value of its intangible assets with indefinite lives may not be recoverable, including, but not limited to, expected growth rates, the cost of equity and debt capital, general economic conditions, the Company's outlook and market performance of the Company's industry and recent and forecasted financial performance.

The Company evaluates indefinite-lived intangible assets for impairment at least annually on the Assessment Date, and whenever facts and circumstances indicate that their carrying amounts may not be recoverable. During the year ended December 31, 2025, the Company recorded a $56.7 million impairment related to its IPR&D asset related to Descartes-08 in systemic lupus erythematosus, or SLE. There was no impairment recorded for the year ended December 31, 2024. See Note 3, "Goodwill and Indefinite-Lived Intangible Assets" for more information.

Convertible Preferred Stock

The Company records its convertible preferred stock upon issuance at its fair value. The fair value includes the original issuance price, the settlement of any related forward contract, and is less issuance costs. The Company classifies its convertible preferred stock outside of stockholders' deficit if the redemption of such shares is outside the Company's control. For shares classified outside of stockholders' deficit, the Company does not adjust the carrying value of its convertible preferred stock to redemption value until it is probable of becoming redeemable. As of December 31, 2025 and 2024, there were no conditions

that could have required cash redemption of the convertible preferred stock and therefore, all convertible preferred stock were classified within stockholders' deficit.

Series A Preferred Stock Options

The Company classifies a portion of the fair value of the vested stock options for Series A Preferred Stock equal to the estimated redemption value on the measurement date outside of stockholders' deficit, if the redemption of the shares underlying the options are outside the Company's control. Any fair value in excess of the estimated redemption value is recognized as additional paid-in capital. The estimated redemption value is based on the intrinsic value of the option. The Company does not adjust the carrying value of the stock options for Series A Preferred Stock until the underlying Series A Preferred Stock is probable of becoming redeemable. The Company records the stock options for Series A Preferred Stock based on the intrinsic value of the vested options.

Variable Interest Entities

The Company evaluates its variable interests in variable interest entities, or VIEs, and consolidates VIEs when the Company is the primary beneficiary. The Company determines whether it is the primary beneficiary of a VIE based on its assessment of whether the Company possesses both (i) the power to direct the activities that most significantly affect the VIE's economic performance and (ii) the obligation to absorb losses that could be significant to the VIE or the right to receive benefits that could be significant to the VIE. The Company reevaluates the accounting for its VIEs upon the occurrence of events that could change the primary beneficiary conclusion. The Company determined that it was more likely than not that its investment in Cyrus was unrecoverable. Therefore, the Company recorded an impairment on its investment of $2.0 million during the year ended December 31, 2025. There was no impairment on investment during the year ended December 31, 2024. See Note 4, "Investment" for more details.

Contingent Value Right Liability

The CVRs distributed by the Company pursuant to the terms of the CVR Agreement (as defined below) represent financial instruments that are accounted for under the fair value option election in ASC Topic 825, Financial Instruments (ASC 825). Under the fair value option election, the CVRs are initially measured at the aggregate estimated fair value of the CVRs and will be subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The estimated fair value of the CVR liability is determined using a Monte Carlo simulation method to estimate future cash flows associated with the legacy assets, including the expected milestone and royalty payments under the Sobi License, net of deductions. Changes in fair value of the liability are presented in the consolidated statements of operations and comprehensive loss. The fair value of the liability is based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of success and expected volatilities of revenues, which represent Level 3 measurements within the fair value hierarchy.

Forward Contract Liabilities

The Company accounts for contracts related to the future issuance of its common stock or convertible preferred stock as a liability if the underlying shares include a redemption feature that may require the Company to settle the instrument by transferring an asset. A forward contract liability is carried at fair value through the date the underlying shares are issued. Subsequent measurement of the fair value of a forward contract liability is based on the market price of the Company's common stock, which represent Level 2 inputs within the fair value hierarchy as it's based on observable market data. Changes in fair value of the liability are presented within change in fair value of forward contract liabilities in the consolidated statements of operations and comprehensive loss.

Recent Accounting Pronouncements

Recently Adopted

In December 2023, the FASB, issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The Company adopted the new standard during the year ended December 31, 2025 and the amendment has been applied prospectively. See Note 16, "Income Taxes" for additional information.

Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement Reporting- Comprehensive Income- Expense Disaggregation Disclosures* (ASU 2024-03), which requires public companies to disclose, in interim and annual reporting periods, additional information about certain expenses in notes to financial statements, including purchases of inventory,

employee compensation, depreciation, amortization of intangible assets, and selling expenses. This guidance will be effective for the annual period beginning the year ended December 31, 2027 and for interim periods beginning January 1, 2028, with early adoption permitted. The Company is currently in the process of evaluating the impact of the standard's adoption on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities* (ASU 2025-10), which establishes authoritative guidance on the recognition, measurement, presentation, and disclosure of government grants. Under ASU 2025-10, government grants are recognized when it is probable that the entity will both comply with the conditions of the grant and the grant will be received. The ASU provides specific accounting models for grants related to assets and grants related to income, including options to recognize government grants as deferred income or as a reduction of the asset's cost basis. The ASU also requires enhanced disclosures regarding the nature of government grants, significant terms and conditions, accounting policies applied, and amounts recognized in the financial statements. ASU 2025-10 is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-10 on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* (ASU 2025-11), which clarifies the guidance in Topic 270 to improve the consistency of interim financial reporting. The ASU provides a comprehensive list of required interim disclosures and introduces a disclosure principle requiring entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. ASU 2025-11 is effective for fiscal years beginning after December 15, 2027, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-11 on its consolidated financial statements and related disclosures.

3. Goodwill and Indefinite-Lived Intangible Assets

On November 13, 2023, the Company merged with Old Cartesian in accordance with the terms of the Merger Agreement. See Note 1, "Description of the Business" for more information. In connection with Merger, the Company recorded goodwill of approximately $48.2 million and total indefinite-lived intangible assets of $150.6 million, of which $93.9 million is related to Descartes-08 for MG and $56.7 million is related to Descartes-08 for SLE.

Indefinite-Lived Intangible Assets

The Company assesses its intangible assets, consisting of IPR&D related to Descartes-08 for MG and Decartes-08 for SLE, for impairment at least annually on the Assessment Date or whenever facts and circumstances indicate that their carrying amounts may not be recoverable. When testing IPR&D for impairment, the Company may assess qualitative factors for its IPR&D to determine whether it is more likely than not that the fair value of its indefinite-lived assets are less than its carrying amount. The qualitative assessment includes the Company's consideration of relevant events and circumstances that would affect the Company's indefinite-lived assets, including macroeconomic, industry and market conditions as well as the Company's financial performance.

For the annual impairment review during the year ended December 31, 2025, the Company performed a qualitative assessment and determined a quantitative impairment test for both indefinite-lived assets was required, whereas only a qualitative assessment was performed during the year ended December 31, 2024.

As a part of the quantitative impairment test of the Company's IPR&D assets as of the Assessment Date, an extensive valuation analysis was performed to determine the fair value of the Company's IPR&D assets using a discounted cash flow approach. The estimates and assumptions used in the discounted cash flow approach are Level 3 inputs and primarily include, but are not limited to, projected revenue, the discount rate, control premiums and probability of success. Based on the analysis performed, the estimated fair value of the Company's IPR&D assets exceeded their respective carrying value as of the Assessment Date and therefore, there was no impairment to IPR&D assets.

On November 13, 2025 the Company announced a pause in further development of Descartes-08 in SLE, following which it made a further decision that it would no longer pursue the development of Descartes-08 in SLE, or the Triggering Event. As the result of the Triggering Event, the Company re-evaluated its IPR&D asset related to Descartes-08 for SLE. Following this assessment, the Company found that the related IPR&D asset was fully impaired. Therefore, the Company recorded a $56.7 million impairment charge to the IPR&D asset related to Decartes-08 for SLE within "Impairment of indefinite-lived intangible and long-lived assets" in the consolidated statements of operations and comprehensive loss during the year ended December 31, 2025. The Triggering Event had no impact on Descartes-08 for MG and therefore no impairment with respect to Descartes-08 in MG was recorded. There were no impairments recorded during the year ended December 31, 2024.

Goodwill

The Company assesses its goodwill for impairment at the reporting unit level at least annually on the Assessment Date and whenever facts and circumstances indicate that their carrying amounts may not be recoverable. When testing goodwill for impairment, the Company may assess qualitative factors for its reporting unit to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill. Alternatively, the Company may bypass this qualitative assessment and perform the quantitative goodwill impairment test.

As a part of the quantitative impairment test of the Company's goodwill as of the Assessment Date, an extensive valuation analysis was performed to determine the fair value of the Company's reporting unit using a discounted cash flow approach. The estimates and assumptions used in the discounted cash flow approach are Level 3 inputs and primarily include, but are not limited to, projected revenue, the discount rate, control premiums and probability of success. Based on the analysis performed, the estimated fair value of the Company's reporting unit exceeded the carrying value as of the Assessment Date, and therefore, there was no impairment to goodwill.

As the result of Triggering Event described above, the Company re-evaluated its goodwill for impairment. The Company used the same valuation approach used as of the Assessment Date, with changes made to estimates and assumptions based on the new facts and circumstances as of the Triggering Event. Based on the analysis performed, the estimated fair value of the Company's reporting unit exceeded the carrying value, and therefore, there was no impairment to goodwill.

There were no changes to the carrying value of the Company's goodwill during the years ended December 31, 2025 and 2024.

4. Investment

In 2021, the Company and Cyrus Biotechnology, Inc., or Cyrus, entered into a stock purchase agreement, or the Series B Preferred Stock Purchase Agreement. Pursuant to the Series B Preferred Stock Purchase Agreement, the Company purchased 2,326,934 shares of Cyrus' Series B Preferred Stock, par value $0.0001 per share, at a purchase price of $0.8595 per share, for $2.0 million.

In accordance with ASC 810, the Company has a variable interest in Cyrus resulting from its equity investment. The Company will share in Cyrus' expected losses or receive a portion of its expected returns and absorb the variability associated with changes in the entity's net assets. However, the Company is not the primary beneficiary as it does not have the power to direct the activities most significant to Cyrus, and therefore it is not required to consolidate Cyrus. The Company recognized the $2.0 million investment of Cyrus' Series B Preferred Stock at cost on the purchase date. The Company has not provided financing to Cyrus other than the amount contractually required by the Series B Preferred Stock Purchase Agreement.

The Company evaluates its investment for impairment whenever events or changes in circumstances indicate that the carrying amount of such investment may be impaired. If a decline in value of the investment is determined to be other than temporary, an impairment loss is recognized in other (expense) income, net in the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2025, the Company determined that it was more likely than not that its investment in Cyrus was unrecoverable. Therefore, the Company recorded an impairment on its investment of $2.0 million and there is no carrying value as of December 31, 2025.

5. Net Loss Per Share Allocable to Common Stockholders

The Company reported a net loss for the years ended December 31, 2025 and 2024. The Company used the treasury stock method to determine the number of dilutive shares for the year ended December 31, 2024. The following table sets forth the

computation of basic and diluted net loss per share allocable to common stockholders (in thousands, except share and per-share data):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss allocable to shares of common stock - basic	(130,302)	(77,424)
Less: Change in fair value of forward contract liability settled in February 2024	—	(446)
Net loss allocable to shares of common stock - diluted	$ (130,302)	$ (77,870)
Denominator:		
Weighted-average common shares outstanding - basic	25,973,329	17,276,822
Plus: Dilutive effect of forward contract liability settled in February 2024	—	81,121
Weighted-average common shares outstanding - diluted	25,973,329	17,357,943
Net loss per share:		
Basic	$ (5.02)	$ (4.48)
Diluted	$ (5.02)	$ (4.49)

The following table represents the potential dilutive shares of common stock excluded from the computation of the diluted net loss per share allocable to common stockholders for all periods presented, as the effect would have been anti-dilutive:

	Year Ended December 31,	
	2025	2024
Common stock options and restricted stock units	2,993,745	2,150,273
Warrants to purchase common stock	692,272	692,523
Series A Preferred Stock	4,026,346	4,026,346
Series B Preferred Stock	437,927	437,927
Total	8,150,290	7,307,069

6. Fair Value Measurements

The following tables present the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash equivalents)	$ 122,724	$ 122,724	$ —	$ —
Total	$ 122,724	$ 122,724	$ —	$ —
Liabilities:				
Warrant liability	$ 141	$ —	$ —	$ 141
Contingent value right liability	392,100	—	—	392,100
Total	$ 392,241	$ —	$ —	$ 392,241

	December 31, 2024			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash equivalents)	$ 39,088	$ 39,088	$ —	$ —
Total	$ 39,088	$ 39,088	$ —	$ —
Liabilities:				
Warrant liability	$ 3,836	$ —	$ —	$ 3,836
Contingent value right liability	395,500	—	—	395,500
Total	$ 399,336	$ —	$ —	$ 399,336

There were no transfers within the fair value hierarchy during the years ended December 31, 2025 and 2024.

Cash, Cash Equivalents, and Restricted Cash

As of December 31, 2025 and 2024, money market funds were classified as cash and cash equivalents on the accompanying consolidated balance sheets as they mature within 90 days from the date of purchase.

As of December 31, 2025, the Company had restricted cash balances relating to secured letters of credit in connection with its real estate leases (see Note 9, "Leases"). The Company's consolidated statement of cash flows includes the following as of December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Cash and cash equivalents	$ 125,139	$ 212,610
Long-term restricted cash	1,735	1,669
Total cash, cash equivalents, and restricted cash	$ 126,874	$ 214,279

Warrants to Purchase Common Stock

In December 2019, the Company issued warrants to purchase common stock in connection with a private placement, or the 2019 Warrants. The outstanding 2019 Warrants expired on December 23, 2024 in accordance with their terms. Pursuant to the terms of the 2019 Warrants, the Company could have been required to settle the 2019 Warrants in cash in the event of certain acquisitions of the Company and, as a result, the 2019 Warrants were required to be measured at fair value and reported as a liability on the balance sheet. On December 20, 2022, the Company amended the terms of the outstanding 2019 Warrants held by certain members of the Board of Directors, or the Amended 2019 Warrants, to remove the cash settlement provision. As a result, the Amended 2019 Warrants were remeasured at fair value on December 20, 2022 and reclassified from a liability to equity on the balance sheet. See Note 11, "Equity" for further discussion on the equity-classified Amended 2019 Warrants.

In April 2022, the Company issued warrants in connection with an underwritten offering, or the 2022 Warrants. Pursuant to the terms of the 2022 Warrants, the Company could be required to settle the 2022 Warrants in cash in the event of an acquisition of the Company under certain circumstances and, as a result, the 2022 Warrants are required to be measured at fair value and reported as a liability on the balance sheet.

The Company recorded the fair value of the 2019 Warrants and the 2022 Warrants upon issuance using the Black-Scholes valuation model and is required to revalue the 2019 Warrants and the 2022 Warrants at each reporting date, with any changes in fair value recorded in the consolidated statements of operations and comprehensive loss. The valuations of the 2019 Warrants and the 2022 Warrants are classified as Level 3 of the fair value hierarchy due to the need to use assumptions in the valuations that are both significant to the fair value measurement and unobservable, including the stock price volatility and the expected life of the 2019 Warrants and the 2022 Warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement. The changes in the fair values of the warrants are reflected in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024.

The estimated fair values of the 2019 Warrants and the 2022 Warrants were determined using the following inputs to the Black-Scholes simulation valuation:

- Estimated fair value of the underlying stock. The Company estimates the fair value of the common stock based on the closing stock price at the end of each reporting period.
- Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury at the valuation date commensurate with the expected remaining life assumption.
- Dividend rate. The dividend rate is based on the historical rate, which the Company anticipates will remain at zero.
- Expected life. The expected life of the 2019 Warrants was assumed to be equivalent to their remaining contractual term which expired on December 23, 2024. The expected life of the 2022 Warrants is assumed to be equivalent to their remaining contractual term which expires on April 11, 2027.
- Volatility. The Company estimates stock price volatility based on the Company's historical volatility for a period of time commensurate with the expected remaining life of the warrants.

The 2019 Warrants expired on December 23, 2024 and therefore, there were no 2019 Warrants outstanding as of December 31, 2025 or 2024.

A summary of the Black-Scholes pricing model assumptions used to record the fair value of the 2022 Warrants liability is as follows:

	December 31,	
	2025	2024
Risk-free interest rate	3.48%	4.25%
Dividend yield	—	—
Expected life (in years)	1.28	2.28
Expected volatility	87.36%	92.92%

The following table reflects a roll-forward of fair value for the Company's Level 3 warrant liability (see Note 11, "Equity"), for the year ended December 31, 2025 (in thousands):

	Warrant liability
Fair value as of December 31, 2024	$ 3,836
Change in fair value	(3,695)
Fair value as of December 31, 2025	$ 141

Contingent Value Right

On December 6, 2023, as contemplated by the Merger Agreement, the Company entered into a contingent value rights agreement, or the CVR Agreement, pursuant to which each holder of common stock or a 2022 Warrant as of December 4, 2023 was distributed a CVR, issued by the Company for each share of common stock held directly or underlying a 2022 Warrant held by such holder as of December 4, 2023. Holders of warrants other than the 2022 Warrants will be entitled to receive, upon exercise of such warrants and in accordance with the terms of the warrants, 30 CVRs per each share of common stock underlying such warrants.

Each CVR entitles its holder to distributions of the following, pro-rated on a per-CVR basis, during the period ending on the date on which the Royalty Term (as defined in the Sobi License) ends, or the Termination Date:

- 100% of all milestone payments, royalties and other amounts paid to the Company or its controlled affiliates, or the Company Entities, under the Sobi License or, following certain terminations of the Sobi License, any agreement a Company Entity enters into that provides for the development and commercialization of Nanoecapsulated Sirolimus plus Pegadricase, or NASP, formerly known as SEL-212; and
- 100% of all cash consideration and the actual liquidation value of any and all non-cash consideration of any kind that is paid to or is actually received by any Company Entity prior to the Termination Date pursuant to an agreement relating to a sale, license, transfer or other disposition of any transferable asset of the Company existing as of immediately prior to the Merger, other than those exclusively licensed under the Sobi License or which the Company Entities are required to continue to own in order to comply with the Sobi License.

The distributions in respect of the CVRs will be made on a semi-annual basis, and will be subject to a number of deductions, subject to certain exceptions or limitations, including for (i) certain taxes payable on the proceeds subject to the CVR distribution, (ii) certain out of pocket costs incurred by the Company Entities, including audit and accounting fees incurred in connection with reporting obligations relating to the CVRs and other expenses incurred in the performance of their obligations and other actions under the CVR Agreement, (iii) a fixed semi-annual amount of $0.75 million for general and administrative overhead, (iv) payments made and remaining obligations on lease liabilities of Selecta immediately prior to the Merger and (v) amounts paid and remaining obligations with regard to the Xork product candidate. Each of the deductions described in (iv) and (v) will be made only if certain milestone payments under the Sobi License are made and are also subject to certain adjustments as contemplated in the CVR Agreement. Upon the achievement of a development milestone in June 2024, Sobi became obligated to make a $30.0 million payment to the Company and made such payment in July 2024. The proceeds from this payment, net of deductions specified in the CVR Agreement, were included in the scheduled distribution to the holders of the CVR in March 2025.

The CVRs represent financial instruments that are accounted for under the fair value option election in ASC 825. Under the fair value option election, the CVRs were initially measured at the aggregate estimated fair value of the CVRs and will be

subsequently remeasured at estimated fair value on a recurring basis at each reporting period date. The liability was recorded at the date of approval, November 13, 2023, as a dividend. The estimated fair value of the CVR liability was determined using a Monte Carlo simulation model as of December 31, 2025 and 2024 to estimate future cash flows associated with the legacy assets, including the expected milestone and royalty payments under the Sobi License, net of deductions. Changes in fair value of the CVR liability are presented in the consolidated statements of operations and comprehensive loss. The fair value of the liability is based on significant inputs not observable in the market such as estimated cash flows, estimated probabilities of success, and expected volatility of future revenues, which represent Level 3 measurements within the fair value hierarchy. The significant inputs used to estimate the fair value of the CVR liability, which represented a financial instrument being accounted for under the fair value option, were as follows:

	December 31,	
	2025	2024
Estimated cash flow dates	2026 - 2037	2025 - 2038
Estimated probability of success	95.0% - 100.0%	95.0% - 100.0%
Expected volatility of future revenues	23.0%	22.0%

The following table reflects a roll-forward of fair value for the Company's Level 3 CVR liability for the year ended December 31, 2025 (in thousands):

	CVR liability
Fair value as of December 31, 2024	$ 395,500
Distributions	(7,754)
Change in fair value	4,354
Fair value as of December 31, 2025	$ 392,100

Forward Contract Liabilities

The Company entered into a contract for the issuance of 149,330.115 shares of Series A Preferred Stock as part of the 2023 Private Placement which was settled in multiple tranches. The Company determined the obligation to issue 148,710.488 shares of Series A Preferred Stock to Timothy A. Springer, Ph.D., a member of the Company's Board of Directors, and TAS Partners LLC, an affiliate of Dr. Springer, represented a forward contract. See Note 10, "Convertible Preferred Stock." The initial fair value of the forward contract liability on November 13, 2023 was insignificant as the fair value of the underlying Series A Preferred Stock was equal to the purchase price of the Series A Preferred Stock as agreed upon in the 2023 Private Placement. Subsequent measurement of the fair value of the forward contract liability was based on the market price of the Company's common stock, which represented the redemption and conversion value of the Series A Preferred Stock, less the purchase price, on an as-converted basis. The non-cash settlement of a portion of the liability occurred on December 13, 2023 with the issuance of the first tranche of the Series A Preferred Stock for $14.8 million. The non-cash settlement of the remaining second and third tranches occurred on January 12, 2024 and February 11, 2024, respectively, for a total of $35.2 million.

7. Property and Equipment

Property and equipment consists of the following (in thousands):

	December 31,	
	2025	2024
Laboratory equipment	$ 8,419	$ 7,295
Computer equipment and software	417	415
Leasehold improvements	4,177	3,427
Furniture and fixtures	269	268
Office equipment	170	169
Construction in process	3,466	695
Total property and equipment	16,918	12,269
Less: Accumulated depreciation	(4,733)	(2,357)
Property and equipment, net	$ 12,185	$ 9,912

See Note 9, “Leases” for details regarding the impairment loss the Company recognized for certain furniture and fixtures during the year ended December 31, 2024.

Depreciation expense was $2.4 million and $1.2 million for the years ended December 31, 2025 and 2024, respectively.

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2025	2024
Payroll and employee related expenses	$ 3,985	$ 3,534
Collaboration and licensing	320	55
Accrued patent fees	205	813
Accrued research and development costs	2,521	2,987
Accrued professional and consulting services	2,059	3,674
Property and equipment	18	782
Other	390	231
Accrued expenses	$ 9,498	$ 12,076

9. Leases

7495 New Horizon Way Leases

On February 28, 2024, the Company entered into a lease agreement with 7495 RP, LLC, or the Landlord, pursuant to which it agreed to lease from the Landlord the manufacturing space located at 7495 New Horizon Way, Frederick, Maryland, or the Frederick Lease Agreement. The space consists of 19,199 leasable square feet of integrated manufacturing and office space. The lease commenced on May 1, 2024 which was the date the Landlord delivered full possession of the premises to the Company. The Frederick Lease Agreement will terminate approximately 7.2 years following the commencement date. The Company will have one option to extend the term of the Frederick Lease Agreement for a period of five years at a cost of 100% of the then-fair market value, not to exceed 103% of the then-current base rent. Base rent, which was due beginning on July 1, 2024, is $0.9 million annually and is subject to an annual upward adjustment of 3% of the then-current rental rate. In addition, the Company is obligated to pay its share of operating costs and taxes related to the property. The Company paid the first month’s rent of $0.1 million upon execution of the Frederick Lease Agreement.

The Company assessed the classification of the lease at the commencement date and concluded it should be accounted for as an operating lease. The Company recorded a lease liability and right-of-use asset of $3.6 million and $3.7 million, respectively, on the commencement date. The Frederick Lease Agreement includes a tenant improvement allowance of up to $0.7 million which was recognized as a reduction in the right-of-use asset and lease liability at the commencement date as the Company was reasonably certain to incur reimbursable costs related to alterations equal to or exceeding the amount. Additionally, the prepaid rent was included as an adjustment to the right-of-use asset. The discount rate of 14% was determined based on the Company’s incremental borrowing rate adjusted for the lease term, including any reasonably certain renewal periods.

Effective May 7, 2024, the Company and the Landlord entered into the first amendment to the Frederick Lease Agreement, or the First Frederick Lease Agreement Amendment, providing for the expansion of the premises leased pursuant to the Frederick Lease Agreement by approximately 7,842 square feet. In connection with the expansion of the leased premises, the Company is obligated to pay $0.3 million in additional annual base rent for the first year of the term, which is subject to an annual upward adjustment of 3% of the then-current rental rate, as well as its share of operating costs and taxes. The lease commenced on May 7, 2024 which was the date the Landlord delivered full possession of the premises to the Company and will be coterminous with the Frederick Lease Agreement. The rent commencement date was September 1, 2024.

The Company assessed the classification of the lease at the commencement date and concluded it should be accounted for as an operating lease. The Company recorded a lease liability and right-of-use asset each of $1.2 million on the commencement date. The First Frederick Lease Agreement Amendment includes a tenant improvement allowance of up to $0.1 million which was recognized as a reduction in the right-of-use asset and lease liability at the commencement date as the Company was reasonably certain to incur reimbursable costs related to alterations equal to or exceeding the amount. The discount rate of 14% was determined based on the Company’s incremental borrowing rate adjusted for the lease term.

Effective August 30, 2024, the Company and the Landlord entered into the second amendment to the Frederick Lease Agreement, or the Second Frederick Lease Agreement Amendment, providing for the expansion of the premises leased pursuant to the Frederick Lease Agreement and First Frederick Lease Agreement Amendment by approximately 2,009 square feet. In connection with the expansion of the leased premises, the Company is obligated to pay $0.1 million in additional annual base rent for the first year of the term, which is subject to an annual upward adjustment of 3% of the then-current rental rate, as well as its share of operating costs and taxes. The lease commenced on September 1, 2024, which was the date the Landlord delivered full possession of the premises to the Company and will be coterminous with the Frederick Lease Agreement. The rent commencement date was September 1, 2024.

The Company assessed the classification of the lease at the commencement date and concluded it should be accounted for as an operating lease. The Company recorded a lease liability and right-of-use asset each of $0.3 million on the commencement date. The discount rate of 14% was determined based on the Company's incremental borrowing rate adjusted for the lease term.

On March 13, 2025, the Company and the Landlord entered into the third amendment to the Frederick Lease Agreement, or the Third Frederick Lease Agreement Amendment, providing for the expansion of the premises leased pursuant to the Frederick Lease Agreement, First Fredrick Lease Agreement Amendment and Second Fredrick Lease Agreement Amendment by approximately 6,439 square feet. In connection with the expansion of the leased premises, the Company is obligated to pay $0.2 million in additional annual base rent for the first year of the term, which is subject to an annual upward adjustment of 3% of the then-current rental rate, as well as its share of operating costs and taxes. The lease commenced on November 1, 2025, which was the date the Landlord delivered full possession of the premises to the Company and will be coterminous with the Frederick Lease Agreement.

The Company assessed the classification of the lease at the commencement date and concluded it should be accounted for as an operating lease. The Company recorded a lease liability and right-of-use asset each of $0.8 million on the commencement date. The discount rate of 14% was determined based on the Company's incremental borrowing rate adjusted for the lease term.

The Company secured a letter of credit from Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as Receiver for Silicon Valley Bridge Bank, N.A. (as successor to Silicon Valley Bank)), or SVB, for $0.3 million for the Frederick Lease Agreement, the First Frederick Lease Agreement Amendment, the Second Frederick Lease Agreement Amendment and the Third Frederick Lease Agreement Amendment which is recognized as long-term restricted cash as of December 31, 2025, and 2024 and renews automatically each year.

65 Grove Street Lease

In July 2019, the Company entered into a lease with BRE-BMR Grove LLC for 25,078 square feet of laboratory and office space located at 65 Grove Street, Watertown, Massachusetts, or the Watertown Lease Agreement. As part of the Watertown Lease Agreement, the Company incurred $0.8 million in non-reimbursable construction costs. The lease began in March 2020, when the Company took control of the office space, and the lease term is 8 years. The discount rate of 8.9% was determined based on the Company's incremental borrowing rate adjusted for the lease term, including any reasonably certain renewal periods. In connection with the Watertown Lease Agreement, the Company secured a letter of credit from SVB for $1.6 million.

On September 1, 2022, the Company entered into an amendment, or the Watertown Lease Agreement Amendment, to its lease agreement with BRE-BMR Grove LLC, originally entered into on July 23, 2019 to expand the Company's laboratory and office space located at 65 Grove Street, Watertown, Massachusetts by 7,216 square feet. The lease term began on September 1, 2022, consistent with when the Company took control of the office space and the expected lease term is 5.7 years. The discount rate of 11.3% was determined based on the Company's incremental borrowing rate adjusted for the lease term including any reasonably certain renewal periods. Rent payments began in November 2022, and the base rent for the first year is $0.1 million per month. The Company recorded the right-of-use asset and operating lease liabilities of $3.2 million during the year ended December 31, 2022 as control of the premises was transferred to the Company.

On October 6, 2022, the Company entered into a sublease agreement to sublease 7,216 square feet of space currently rented by the Company at 65 Grove Street, Watertown, Massachusetts. The sublease commenced on October 24, 2022, when the Company, the sublessee and BRE-BMR Grove LLC, executed a Consent to Sublease. The term of the sublease expired on March 31, 2024 with no option to extend the sublease term. Sublease income is included within other income, net in the consolidated statements of operations and comprehensive loss.

As a result of the sublease agreement and Consent to Sublease, rent payments to BRE-BMR Grove LLC for the lease of the office space increased. The change of consideration in the contract was accounted for as a lease modification and the right-of-use asset and lease liability were remeasured at the modification date of October 24, 2022. The discount rate of 11.9% was determined based on the Company's incremental borrowing rate adjusted for the lease term including any reasonably certain

renewal periods as of October 24, 2022, resulting in a decrease of less than $0.1 million to both the right-of-use asset and lease liabilities.

In May 2023, the Company received notice from BRE-BMR Grove LLC that the requirements to reduce the amount of the letter of credit for the Watertown Lease Agreement had been met. In connection therewith, in June 2023, the Company secured a letter of credit from JPMorgan Chase Bank, N.A. for $1.4 million, which is recognized as long-term restricted cash as of December 31, 2025 and 2024, and renews automatically each year.

On October 31, 2023, in connection with entering into Amendment No. 1 to the License and Development Agreement with Sobi as described in Note 13 “Revenue Arrangements,” the Company entered into a sublease agreement with Sobi to sublease approximately 5,600 square feet of space currently rented by the Company at 65 Grove Street, Watertown, Massachusetts for which Sobi paid $1.0 million upfront rental payment. The sublease commenced on November 6, 2023, when the Company, Sobi, and BRE-BMR Grove LLC, executed a Consent to Sublease. The term of the sublease expired on November 5, 2024 with no option to extend the sublease term.

As a result of the expiration of the sublease to Sobi in November 2024 and the Company’s decision to cease use of its office and laboratory space at 65 Grove Street, Watertown, Massachusetts, the Company assessed the right-of-use assets and related furniture and fixtures associated with the Watertown Lease Agreement and Watertown Lease Agreement Amendment for impairment. The carrying value of each asset group was compared against the future net undiscounted cash flows projected to be generated over the remaining lease terms. These projections included management's estimates of cash inflows from potential sublease income. The carrying amount of the asset groups was found to be unrecoverable, thus the Company assessed the fair value of each asset group. The fair value was determined using the income approach, whereby the Company discounted the estimated net cash flows using a rate commensurate with the Company’s estimated incremental borrowing rate. As a result of this assessment, which included unrecoverable operating and maintenance costs, the Company determined that each asset group was fully impaired. As such, an impairment charge of $7.6 million was recognized during the year ended December 31, 2024 within “Impairment of indefinite-lived intangible and long-lived assets” in the consolidated statements of operations and comprehensive loss, $7.4 million of which related to the right-of-use assets and $0.2 million related to property and equipment.

704 Quince Orchard Road Leases

In connection with the Merger, the Company acquired two operating leases for office and laboratory space in Gaithersburg, Maryland. The leases expire in January 2027 and do not contain any renewal rights. The discount rate of 11.5% was determined based on the Company’s incremental borrowing rate adjusted for the lease term.

Rent expense for the years ended December 31, 2025 and 2024 was $4.2 million and $5.5 million, respectively.

For the years ended December 31, 2025 and 2024, the components of lease costs were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 2,287	$ 3,856
Variable lease cost	1,724	1,609
Short-term lease cost	221	28
Less sublease income	—	(1,099)
Total lease cost	$ 4,232	$ 4,394

The maturity of the Company's operating lease liabilities as of December 31, 2025 were as follows (in thousands):

	December 31, 2025
2026	$ 4,740
2027	4,554
2028	2,529
2029	1,630
2030	1,679
Thereafter	852
Total future minimum lease payments	15,984
Less: Imputed interest	(3,308)
Total operating lease liabilities	$ 12,676

The supplemental disclosure for the statement of cash flows related to operating leases were as follows (in thousands):

	December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:	$ 3,662	$ 3,559

Other than the initial recording of the right-of-use assets and lease liabilities for the Third Fredrick Lease Amendment during year ended December 31, 2025, and the Frederick Lease Agreement, First Frederick Lease Agreement Amendment, the Second Frederick Lease Agreement Amendment and impairment on the right-of-use assets for the Watertown Lease Agreement and Watertown Lease Agreement Amendment during the year ended December 31, 2024, which were non-cash, the changes in the Company's right-of-use assets and lease liabilities for the years ended December 31, 2025 and 2024 are reflected in the non-cash lease expense and accrued expenses and other liabilities, respectively, in the consolidated statements of cash flows.

The following summarizes additional information related to the Company's operating leases:

	December 31,	
	2025	2024
Weighted-average remaining lease term	3.9 years	4.5 years
Weighted-average discount rate	12.1%	11.7%

10. Convertible Preferred Stock

Series B Preferred Stock

The Certificate of Designation of Preferences, Rights, and Limitations of the Series B Non-Voting Convertible Preferred Stock, or the Series B Certificate of Designation, was filed with the Secretary of State of the State of Delaware on July 2, 2024,

and provided for the designation of shares of Series B Preferred Stock and authorized the issuance of 2,937,903 shares of Series B Preferred Stock.

Additionally, on July 2, 2024, the Company entered into a securities purchase agreement, or the 2024 Securities Purchase Agreement, for a private investment in public equity financing, or the 2024 Private Placement, which provided for the issuance of 3,563,247 shares of common stock and 2,937,903 shares of Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share, or the Series B Preferred Stock, each at a purchase price of $20.00 per share to certain institutional and accredited investors, or the Purchasers. The Purchasers included (i) Timothy A. Springer, Ph.D., a member of the Company's Board of Directors; (ii) TAS Partners LLC, an affiliate of Dr. Springer, and (iii) Chafen Lu, Ph.D., Dr. Springer's wife. Pursuant to the 2024 Securities Purchase Agreement, the Company agreed to issue and sell an aggregate of 3,563,247 shares of common stock and 2,937,903 shares of Series B Preferred Stock for an aggregate purchase price of $130.0 million in the 2024 Private Placement. Each share of Series B Preferred Stock is convertible into one share of the Company's common stock subject to stockholder approval of a proposal to issue such shares of common stock upon conversion of such shares of Series B Preferred Stock in accordance with the Listing Rules of the Nasdaq Stock Market LLC, or the Series B Conversion Proposal.

Under the 2024 Securities Purchase Agreement, the Company issued 3,563,247 shares of common stock and 578,403 shares of Series B Preferred Stock for an aggregate purchase price of $82.8 million to the Purchasers other than Dr. Springer, TAS Partners LLC, and Dr. Lu. The Company also issued (i) 1,636,832 shares of Series B Preferred Stock to Dr. Springer, (ii) 721,361 shares of Series B Preferred Stock to TAS Partners LLC, and (iii) 1,307 shares of Series B Preferred Stock to Dr. Lu for an aggregate purchase price of $47.2 million.

Pursuant to the 2024 Securities Purchase Agreement, the Company agreed to submit to its stockholders the approval of the Series B Conversion Proposal, at a special meeting of stockholders, which was held on September 20, 2024. On September 20, 2024, at such special meeting, the Company's stockholders approved the Series B Conversion Proposal, among other matters. On September 25, 2024, pursuant to the terms of the Series B Certificate of Designation, 2,499,976 shares of Series B Preferred Stock automatically converted into 2,499,976 shares of common stock; 437,927 shares of Series B Preferred Stock did not automatically convert at such time due to beneficial ownership limitations.

The Series B Preferred Stock were classified in permanent equity as there were no conditions that could have required cash redemption of the shares.

The Series B Preferred Stock has the following rights and preferences:

- *Conversion:* Prior to the stockholder approval of the Series B Conversion Proposal the Series B Preferred Stock were not convertible into shares of common stock. Following the stockholder approval of the Series B Conversion Proposal, each share of Series B Preferred Stock automatically converted into one share of common stock, subject to certain limitations, including that a holder of Series B Preferred Stock is prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be established by the holder between 0.0% and 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion; provided, however, that such beneficial ownership limitation does not apply to Dr. Springer, TAS Partners LLC, or any of their respective affiliates. Each share of Series B Preferred Stock outstanding that was not automatically converted into common stock as a result of the stockholder approval of the Series B Conversion Proposal shall be convertible at any time at the option of the holder following stockholder approval of the Series B Conversion Proposal, only to the extent the beneficial ownership limitation does not apply to the shares of Series B Preferred Stock to be converted.
- *Redemption:* The Series B Preferred Stock is not redeemable.
- *Dividends:* Holders of Series B Preferred Stock are entitled to receive dividends on shares of Series B Preferred Stock on an as-converted basis (without regard to the beneficial ownership limitation) equal to the dividends paid on shares of the common stock.
- *Voting:* Except as otherwise required by law, the Series B Preferred Stock does not have voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, (b) alter or amend the Series B Certificate of Designation, or (c) amend the Charter or other organizational documents in any manner that alters or changes the preferences, rights, privileges, or powers of, or restrictions provided for the benefit of the holders of Series B Preferred Stock.
- *Liquidation:* The holders of Series B Preferred Stock shall rank on parity with the holders of common stock and the holders of Series A Preferred Stock as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, each holder of Series B Preferred Stock shall be entitled to receive out of the assets of the Company, whether capital or surplus, the same amount that a holder of common stock would receive if the Series B Preferred Stock were fully converted, which shall be paid pari passu with holders of common stock and holders of Series A Preferred Stock, plus an amount equal to any dividends declared but unpaid. If the assets available for distribution are not sufficient to pay the holders of the Series B Preferred Stock pursuant to the preceding sentence, all remaining assets will be distributed ratably to the holders of the Series A Preferred Stock, Series B Preferred Stock and common stock.

Series A Preferred Stock

The Certificate of Designation of Preferences, Rights, and Limitations of the Series A Non-Voting Convertible Preferred Stock, or the Series A Certificate of Designation, was filed on November 13, 2023, which provided for the designation of shares of the Series A Preferred Stock and authorized the issuance of 548,375 shares of Series A Preferred Stock.

Additionally on November 13, 2023, the Company entered into the 2023 Securities Purchase Agreement with (i) Timothy A. Springer, Ph.D., a member of the Company's Board of Directors; (ii) TAS Partners LLC, an affiliate of Dr. Springer, and (iii) Seven One Eight Three Four Irrevocable Trust, a trust associated with Murat Kalayoglu, M.D. Ph.D., a co-founder and the former chief executive officer of Old Cartesian, who joined the Company's Board of Directors effective immediately after the effective time of the Merger, or the Investors. Pursuant to the 2023 Securities Purchase Agreement, the Company agreed to issue and sell an aggregate of 149,330.115 shares of Series A Preferred Stock for an aggregate purchase price of $60.25 million in the 2023 Private Placement.

In the 2023 Private Placement, Dr. Springer agreed to settle his purchases in three tranches of shares of Series A Preferred Stock, the first for a purchase price of $10.0 million and each thereafter for a purchase price of approximately $20.0 million, with the three tranches settling 30, 60, and 90 days, respectively, following the Closing Date. TAS Partners LLC agreed to settle its purchase for approximately $10.0 million within 30 days following the Closing Date. The first, second and third tranches were settled on December 13, 2023, January 12, 2024 and February 11, 2024, respectively, under which (i) 24,785.081 shares of Series A Preferred Stock were issued to each of TAS Partners LLC and Dr. Springer in the first tranche, (ii) 49,570.163 shares of Series A Preferred Stock were issued to Dr. Springer in the second tranche, and (iii) 49,570.163 shares of

Series A Preferred Stock were issued to Dr. Springer in the third tranche. On November 15, 2023, the Company issued 619.627 shares of Series A Preferred Stock to Seven One Eight Three Four Irrevocable Trust for $0.25 million.

The Company determined the obligation to issue 148,710.488 shares of Series A Preferred Stock to Dr. Springer and TAS Partners LLC represented a forward contract and was accounted for as a liability with changes in fair value recorded in earnings. A portion of the liability was settled with the initial issuance of 49,570.162 shares of Series A Preferred Stock on December 13, 2023. The remaining portion of the forward contract liability was settled upon the issuance of 49,570.163 shares of Series A Preferred Stock each on January 12, 2024 and February 11, 2024, respectively (see Note 6, “Fair Value Measurements”).

On December 5, 2023, the Company issued 384,930.724 shares of Series A Preferred Stock as part of its consideration transferred in connection with the Merger which settled the related forward contract liability (see Note 6, “Fair Value Measurements”).

On March 26, 2024, the Company, with the consent of the requisite holders of Series A Preferred Stock, amended the Series A Certificate of Designation such that the automatic conversion of the Series A Preferred Stock into common stock, or the Automatic Conversion, would occur eight business days following stockholder approval of the Conversion Proposal.

On March 27, 2024, the Company’s stockholders approved the Conversion Proposal, among other matters, at the Special Meeting.

On April 8, 2024, pursuant to the terms of the Series A Certificate of Designation, as amended, 367,919.247 shares of Series A Preferred Stock automatically converted into 12,263,951 shares of common stock, including the non-cash reclassification of an amount equal to the increase in par value of common stock from additional paid-in capital; 166,341.592 shares of Series A Preferred Stock did not automatically convert at such time due to beneficial ownership limitations.

On October 11, 2024, pursuant to a Notice of Optional Conversion delivered to the Company by a holder of Series A Preferred Stock pursuant to the Series A Certificate of Designation, 45,551.190 shares of Series A Preferred Stock held by such holder were converted into 1,518,373 newly issued shares of common stock.

In accordance with the guidance in ASC Topic 480, Distinguishing Liabilities from Equity (ASC 480) the Series A Preferred Stock was classified outside of stockholders’ deficit upon issuance and as of December 31, 2023 because the shares of Series A Preferred Stock contained redemption features that were not solely within the control of the Company. The Series A Preferred Stock was not currently redeemable, nor was it probable that the instrument would become redeemable, as it was only redeemable upon the occurrence of a contingent event. Accordingly, no accretion was recognized for the Series A Preferred Stock. As a result of the approval of the Conversion Proposal, all conditions that could have required cash redemption of the Series A Preferred Stock were removed. Since the Series A Preferred Stock was no longer redeemable, the associated balances of the Series A Preferred Stock were reclassified to permanent equity during the first quarter of 2024.

The Series A Preferred Stock has the following rights and preferences:

- *Conversion:* Prior to the stockholder approval of the Conversion Proposal, the Series A Preferred Shares were not convertible. Following the stockholder approval of the Conversion Proposal, each share of Series A Preferred Stock automatically converted into 33.333 shares of common stock, subject to certain limitations, including that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be established by the holder between 0% and 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion; provided, however, that such beneficial ownership limitation does not apply to Dr. Springer, TAS Partners LLC, or any of their respective affiliates. Each share of Series A Preferred Stock outstanding that was not otherwise automatically converted into common stock as a result of the beneficial ownership limitation shall be convertible at any time at the option of the holder following stockholder approval of the Conversion Proposal, only to the extent the beneficial ownership limitation does not apply to the shares of Series A Preferred Stock to be converted.

- *Redemption:* Prior to the stockholder approval of the Conversion Proposal, each share of Series A Preferred Stock was redeemable at the option of the holder at any time following the date that was 18 months after the initial issuance date of the Series A Preferred Stock, other than any shares of Series A Preferred Stock that would not have been convertible into shares of common stock as a result of the beneficial ownership limitation referred to above. The amount payable upon redemption would have been equal to the average closing sale price of the common stock listed over the ten consecutive trading days ending on, and including, the day immediately prior to the redemption date multiplied by the number of shares of common stock the Series A Preferred Stock would have been convertible into. Following the Conversion Proposal, the Series A Preferred Stock is not redeemable.

- *Dividends:* Holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock on an as-converted basis equal to the dividends paid on shares of the common stock; provided, however, that holders of Series A Preferred Stock (or any shares of common stock into which the Series A Preferred Stock are convertible) are not entitled to any CVRs or any amounts paid under the CVR Agreement.

- *Voting:* Except as otherwise required by law, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock, (b) alter or amend the Series A Certificate of Designation, (c) amend the Charter or other organizational documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (d) issue further shares of Series A Preferred Stock (other than in connection with the exercise of the stock options to purchase Series A Preferred Stock) or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock, (e) prior to the stockholder approval of the Conversion Proposal or at any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, consummate either (A) a Fundamental Transaction (as defined in the Series A Certificate of Designation) or (B) any merger or consolidation of the Company or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, (f) amend or fail to comply with, in any manner that would be reasonably likely to prevent, impede or materially delay the conversion (or the stockholder approval thereof), or terminate, any of the stockholder support agreements entered into in connection with the Merger, or the Support Agreements, or agree to any transfer, sale or disposition of such shares subject to the Support Agreements (except for such transfers, sales or dispositions with respect to which the approval of the Company is not required pursuant to the applicable Support Agreement) or (g) enter into any agreement with respect to any of the foregoing.

- *Liquidation:* The holders of Series A Preferred Stock shall rank on parity with the common stockholders and the holders of Series B Preferred Stock as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary each holder of Series A Preferred Stock shall be entitled to receive out the assets of the Company equal to of the same amount that a holder of common stock would receive if the Series A Preferred Stock were fully converted, which shall be paid pari passu with holders of common stock and holders of Series B Preferred Stock, plus an amount equal to any dividends declared but unpaid. If the assets available for distribution are not sufficient to pay the holders of the Series A Preferred Stock pursuant to the preceding sentence, the assets will be distributed ratably to the holders of the Series A Preferred Stock, Series B Preferred Stock and common stock.

As of December 31, 2025, the Company had 120,790.402 shares of Series A Preferred Stock and 437,927 shares of Series B Preferred Stock issued and outstanding, respectively, which are convertible into a total of 4,464,273 shares of common stock.

11. Equity

Equity Financings

"At the Market" Sales Agreement

On December 13, 2024, the Company entered into a Sales Agreement, or the Sales Agreement, with Leerink Partners to sell shares of the Company's common stock, from time to time, through an "at the market" equity offering program under which Leerink Partners will act as sales agent. The shares of common stock sold pursuant to the Sales Agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-283803), filed on December 13, 2024 with the SEC and related prospectus supplement, filed on January 8, 2025 with the SEC, for aggregate gross sales proceeds of up to $100.0 million. As of December 31, 2025, no shares have been sold pursuant to the Sales Agreement.

2024 Private Placement

On July 2, 2024, the Company and the Purchasers entered into the 2024 Securities Purchase Agreement for the 2024 Private Placement, which provided for the issuance of 3,563,247 shares of common stock and 2,937,903 shares of Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share, or the Series B Preferred Stock, each at a purchase price of $20.00 per share. The 2024 Private Placement resulted in gross proceeds of approximately $130.0 million before deducting placement agent fees and other offering expenses. See Note 10, "Convertible Preferred Stock."

Warrants

The following is a summary of warrant activity for the years ended December 31, 2025 and 2024:

	Number of Warrants			
	Equity classified	Liability classified	Total	Weighted average exercise price
Outstanding at December 31, 2023	74,420	966,393	1,040,813	$ 45.98
Exercises	(65,681)	—	(65,681)	$ 43.80
Expired	(1,928)	(280,681)	(282,609)	$ 44.09
Outstanding at December 31, 2024	6,811	685,712	692,523	$ 46.96
Expired	(251)	—	(251)	$ 526.50
Outstanding at December 31, 2025	6,560	685,712	692,272	$ 46.76

During the years ended December 31, 2025 and 2024, the Company recorded a gain of $3.7 million and $2.6 million, respectively, on the change in the fair value of the warrants in the consolidated statements of operations and comprehensive loss.

Common Stock

On April 4, 2024, the Company implemented the Reverse Stock Split. The Reverse Stock Split became effective at 4:30 p.m. Eastern Time on April 4, 2024. On April 5, 2024, the Company's common stock began trading on The Nasdaq Global Market on a split-adjusted basis under the symbol "RNAC" with a new CUSIP number, 816212302. As a result of the Reverse Stock Split, every 30 shares of common stock outstanding were combined, automatically and without any action on the part of the Company or its stockholders, into one share of common stock. Stockholders entitled to fractional shares as a result of the Reverse Stock Split received a cash payment in lieu of receiving fractional shares. The Reverse Stock Split did not change the number of authorized shares or par value of the Company's common or preferred stock.

As of December 31, 2025, the Company had 350,000,000 shares of common stock authorized for issuance, $0.0001 par value per share, with 26,011,106 shares issued and outstanding. The voting, dividend and liquidation rights of the common stockholders are subject to and qualified by the rights, powers and preferences of the preferred stock. The common stock has the following characteristics:

Voting

Common stockholders are entitled to one vote for each share of common stock held with respect to all matters voted on by the stockholders of the Company.

Dividends

Common stockholders are entitled to receive dividends, if and when declared by the Board of Directors. Through December 31, 2025, no cash dividends have been declared or paid on common stock.

Liquidation

Upon liquidation of the Company, common stockholders are entitled to receive all assets of the Company available for distribution to such stockholders.

Reserved Shares

The Company has authorized shares of common stock for future issuance as of December 31, 2025 as follows:

	December 31, 2025
Exercise of warrants	692,021
Shares available for future stock incentive awards	4,148,684
Common stock options reserved for issuance	7,500
Unvested restricted stock units	522,498
Outstanding common stock options	2,463,747
Series A Preferred Stock	4,026,346
Series B Preferred Stock	437,927
Total	12,298,723

12. Stock Incentive Plans

The Company maintained the 2008 Stock Incentive Plan, or the 2008 Plan, for employees, consultants, advisors, and directors. The 2008 Plan provided for the granting of incentive and non-qualified stock option and restricted stock awards as determined by the Board of Directors. In connection with the Merger, all outstanding awards issued under the 2008 Plan were cancelled, and the Board of Directors formally terminated the 2008 Plan.

In June 2016, the Company's stockholders approved the 2016 Incentive Award Plan, or the 2016 Plan, which authorized 40,341 shares of common stock for future issuance under the 2016 Plan and the Company ceased granting awards under the 2008 Plan. Upon the effective date of the 2016 Plan, awards issued under the 2008 Plan remained subject to the terms of the 2008 Plan. Awards granted under the 2008 Plan that expired, lapsed or terminated became available under the 2016 Plan as shares available for future grants.

Additionally, pursuant to the terms of the 2016 Plan, the Board of Directors is authorized to grant awards with respect to common stock, and may delegate to a committee of one or more members of the Board of Directors or executive officers of the Company the authority to grant options and restricted stock units. On December 9, 2020, the Board of Directors established a Stock Option Committee authorized to grant awards to certain employees and consultants subject to conditions and limitations within the 2016 Plan. In June 2024, the Company's stockholders approved an amendment and restatement of the 2016 Plan to reserve an additional 3,466,544 shares of the Company's common stock for issuance. In January 2025, the number of shares of common stock that may be issued under the 2016 Plan was increased by 1,030,694. As of December 31, 2025, 3,594,407 shares remain available for future issuance under the 2016 Plan.

In September 2018, the Company's 2018 Employment Inducement Incentive Award Plan, or the 2018 Inducement Incentive Award Plan was adopted by the Board of Directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules, which authorized 39,166 shares of its common stock for issuance. In March 2019, the Board of Directors approved an amendment and restatement of the 2018 Inducement Incentive Award Plan to reserve an additional 66,667 shares of the Company's common stock for issuance thereunder. In December 2023, the Board of Directors approved an amendment and restatement of the 2018 Inducement Incentive Award Plan to reserve an additional 60,833 shares of the Company's common stock for issuance thereunder. In June and December 2024, the Board of Directors approved amendments and restatements of the 2018 Inducement Incentive Award Plan to reserve an additional 360,000 and 450,000 shares, respectively, of the Company's common stock for issuance thereunder. As of December 31, 2025, there are 472,303 shares available for future grant under the 2018 Inducement Incentive Award Plan.

In accordance with the Merger Agreement, the Company assumed Old Cartesian's 2016 Stock Incentive Plan, or the Old Cartesian Plan. The Old Cartesian Plan permits the granting of options or restricted stock to employees, officers, directors, consultants and advisors to the Company. The unvested common stock options and Series A Preferred Stock options assumed

by the Company in connection with the Merger generally vest over a four-year period. Additionally, the stock options granted have a contractual term of ten years and only full shares can be exercised as per the individual award agreements. As of December 31, 2025, there are 36,179 shares available for future grant under the Old Cartesian Plan.

In connection with the Merger, the outstanding stock options to purchase Old Cartesian common stock were converted into stock options to purchase 776,865 shares of common stock and 14,112.299 shares of Series A Preferred Stock of the Company. These replacement awards were revalued at their acquisition-date fair value and then attributed to pre and post-combination service. This resulted in $2.6 million attributed to post-combination service to be recognized as stock-based compensation expense over the remaining terms of the replacement awards, of which $0.6 million and $1.3 million was recognized as research and development expense in the consolidated statements of operations and comprehensive loss during the years ended December 31, 2025 and 2024, respectively. Following the Automatic Conversion, the options exercisable for shares of Series A Preferred Stock became exercisable for shares of common stock.

Stock-Based Compensation Expense

In April 2025, the Company entered into a separation agreement and release, or the Kurtoglu Separation Agreement, with the Company's former Chief Technology Officer, Metin Kurtoglu, M.D., Ph.D. Dr. Kurtoglu's employment with the Company ended effective May 2025, and Dr. Kurtoglu agreed to serve as a consultant to the Company from May 2025 through April 2026, or the Kurtoglu Consulting Period. Pursuant to the Kurtoglu Separation Agreement, certain of Dr. Kurtoglu's stock options and restricted stock unit awards were modified to accelerate the vesting of a portion of the awards, continue the vesting of the remaining awards during the Kurtoglu Consulting Period, and extend the post-termination exercise period of the modified stock options. The services performed during the Kurtoglu Consulting Period do not qualify as substantive services under ASC 718 and therefore, the continued vesting of these awards represents a modification to the original award. The modification resulted in the recognition of $0.7 million compensation expense during the year ended December 31, 2025, which is reflected in research and development expenses on the consolidated statements of operations and comprehensive loss.

In October 2025, the Company entered into a separation agreement and release, or the Jewell Separation Agreement, with the Company's former Chief Scientific Officer, Chris Jewell, Ph.D. Dr. Jewell's employment with the Company ended effective November 2025, and Dr. Jewell will serve as a consultant to the Company from November 2025 to January 2026, or the Jewell Consulting Period. Pursuant to the Jewell Separation Agreement, certain of Dr. Jewell's stock options and restricted stock unit awards were modified to continue the vesting of the remaining awards during the Jewell Consulting Period and extend the post-termination exercise period of the modified stock options. The services performed during the Jewell Consulting Period do not qualify as substantive services under ASC 718 and therefore, the continued vesting of these awards represents a modification to the original award. The modification resulted in the recognition of a reversal of $0.2 million in compensation expense during the year ended December 31, 2025, which is reflected in research and development expenses on the consolidated statements of operations and comprehensive loss.

Stock-based compensation expense by classification included within the consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 4,772	$ 3,217
General and administrative	5,749	3,365
Total stock-based compensation expense	$ 10,521	$ 6,582

Stock Options

The estimated grant date fair values of stock option awards granted under the 2016 Plan and the 2018 Inducement Incentive Award Plan were calculated using the Black-Scholes option pricing model based on the following weighted-average assumptions:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.36%	4.02%
Dividend yield	—	—
Expected term	6.18	6.21
Expected volatility	96.84%	95.21%
Weighted-average fair value of common stock	$ 16.23	$ 19.63

The expected term of the Company's stock options granted has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. Under the simplified method, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data and the plain nature of its stock-based awards. Expected volatilities are based on the Company's historical volatility.

The weighted average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $13.01 and $15.63, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $0.7 million and $7.0 million, respectively.

As of December 31, 2025, total unrecognized compensation expense related to unvested common stock options was $12.0 million, which is expected to be recognized over a weighted average period of 2.6 years.

The following table summarizes the stock option activity under the 2016 Plan, the 2018 Inducement Incentive Award Plan, and the Old Cartesian Plan for options for common stock:

	Number of common stock options	Weighted-average exercise price ($)	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2024	1,706,035	$ 11.99	7.59	$ 12,025
Granted	1,150,259	$ 16.23		
Reserved for issuance	(7,500)	$ 3.30		
Exercised	(90,444)	$ 3.29		
Forfeited	(294,603)	$ 17.01		
Outstanding at December 31, 2025	2,463,747	$ 13.72	6.41	$ 2,962
Vested at December 31, 2025	909,242	$ 7.95	4.07	$ 2,808
Vested and expected to vest at December 31, 2025	2,197,439	$ 13.29	6.49	$ 2,962

As a result of the approval of the Conversion Proposal on March 27, 2024, all conditions that could have required cash redemption of the Series A Preferred Stock underlying the stock options were removed. Since the Series A Preferred Stock was no longer redeemable, the associated balances of the stock options to purchase Series A Preferred Stock were reclassified to additional paid-in capital during the first quarter of 2024.

Following the Automatic Conversion, all options to purchase Series A Preferred Stock were converted into options to purchase common stock with adjustments to the underlying number of shares of common stock determined by multiplying the number of shares of Series A Preferred Stock by 33.333 and rounding down to the nearest whole number of shares and the per-share exercise price by dividing the per-share exercise price of Series A Preferred Stock by 33.333 and rounding the resulting exercise price up to the nearest whole cent.

Restricted Stock Units

During the year ended December 31, 2025, the Company granted 262,590 restricted stock unit awards with a weighted average fair value of $16.74 per share based on the closing price of the Company's common stock on the date of grant under the 2016 Plan, which generally vest over a four-year term. Forfeitures are estimated at the time of grant and are adjusted, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has estimated a forfeiture rate of 10% for restricted stock unit awards based on historical experience.

The aggregate fair value of restricted stock unit awards that vested during year ended December 31, 2025 was $2.4 million. No restricted stock unit awards vested during the year ended December 31, 2024.

Unrecognized compensation expense related to the restricted stock unit awards was $4.9 million as of December 31, 2025, which is expected to be recognized over a weighted-average period of 2.3 years.

The following table summarizes the Company's restricted stock units under the 2016 Plan and the Old Cartesian Plan:

	Number of shares	Weighted average grant date fair value ($)
Unvested at December 31, 2024	444,238	$ 19.86
Granted	262,590	$ 16.74
Vested	(153,293)	$ 19.86
Forfeited	(31,037)	$ 17.41
Unvested at December 31, 2025	522,498	$ 18.44

13. Revenue Arrangements

Collaboration and license revenue

Astellas Gene Therapies

In January 2023, the Company entered into the License and Development Agreement, or the Astellas Agreement, with Audentes Therapeutics, Inc., or Astellas. Under the Astellas Agreement, the Company granted Astellas an exclusive license to the Company's IdeXork technology arising from Xork, to develop and commercialize Xork for use in Pompe disease in combination with an Astellas gene therapy investigational or authorized product. Xork, Genovis' IgG Protease, was licensed pursuant to an Exclusive License Agreement, or the Genovis Agreement, with Genovis AB (publ.), or Genovis, as described in Note 15, "Collaboration and License Agreements". Astellas paid a $10.0 million upfront payment to the Company upon signing of the Astellas Agreement, and the Company was entitled to receive up to $340.0 million in future additional payments over the course of the partnership that were contingent on the achievement of various development and regulatory milestones and, if commercialized, sales thresholds for annual net sales where Xork is used as a pre-treatment for an Astellas investigational or authorized product. The Company was also eligible for tiered royalty payments ranging from low to high single digits. Any proceeds received from milestone payments or royalties relating to Xork would have been required to be distributed to holders of CVRs, net of certain deductions.

Pursuant to the Astellas Agreement, the Company would have had the exclusive right and responsibility to complete research and development of Xork products and to conduct all preclinical studies and clinical trials for Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product, or the Xork Development Services. Astellas reimbursed the Company for 25% of all budgeted costs incurred to complete the development of Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product. The Company would have had control and responsibility over regulatory filings, including any investigational drug applications, biologics license applications, and marketing authorization applications relating to the licensed product. Astellas would have had the exclusive right and responsibility to research, develop, and commercialize Astellas products used in combination with Xork and would have had control and responsibility over all regulatory filings, including any investigational drug applications, biologics license applications, and marketing authorization applications, relating to Astellas products and Astellas products used in combination with Xork.

The Company determined the Astellas Agreement represented a service arrangement under the scope of ASC 606. The Company determined that the sublicense of Xork to Astellas, the licensed know-how, and the Xork Development Services represented a single promise and performance obligation to be transferred to Astellas over time due to the nature of the promises in the contract. As such, the Company recognized the transaction price as revenue utilizing the input method to measure the progress of satisfying the single performance obligation to Astellas.

In determining the transaction price, the Company concluded the upfront payment of $10.0 million and development cost reimbursements of $5.5 million would be included in the initial transaction price. All other development milestones would be fully constrained and would only have been included in the transaction price when the applicable milestone was deemed probable of achievement. Each of these variable consideration items were evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should have been constrained until they became probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt and timing of such development milestones was outside the control of the Company and probability of success criteria was estimated. The Company re-evaluated the transaction price in each reporting period, as uncertain events were resolved, or as other changes in circumstances occurred. In accordance with ASC 606, the Company would have only recognized revenue associated with sales-based milestones and royalties when the subsequent sales thresholds were reached and underlying sales occurred, respectively. The Company determined that a significant financing component did not exist in its arrangement with Astellas. The Company also determined the options to negotiate additional fields, enter into a clinical supply agreement, and

enter into a commercial supply agreement did not represent material rights under the Astellas Agreement. Astellas had the right to terminate the Astellas Agreement in its entirety or on a field-by-field basis, upon 90 days' written notice to the Company.

In March 2024, the Company was notified by Astellas of its intention to terminate the Astellas Agreement, which occurred effective June 6, 2024.

As of December 31, 2025 and 2024, there were no unsatisfied performance obligations related to the Astellas Agreement. As of December 31, 2025 the Company had no receivable balance related to the Astellas Agreement. As of December 31, 2024, the Company recorded a receivable of $0.1 million, representing billings for the Xork Development Services that were subject to reimbursement by Astellas. No revenue related to the Astellas Agreement was recognized during the year ended December 31, 2025. Revenue of $6.3 million related to the Astellas Agreement was recognized during the year ended December 31, 2024, inclusive of $3.2 million of revenue recognized from performance obligations related to prior periods as a result of the change in transaction price during the year ended December 31, 2024.

Swedish Orphan Biovitrum AB (publ.)

License and Development Agreement

On June 11, 2020, the Company and Sobi entered into a License and Development Agreement. Pursuant to the Sobi License, the Company agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize the NASP drug candidate, which is currently in development for the treatment of chronic refractory gout. The NASP drug candidate is a pharmaceutical composition containing a combination of SEL-037, or the Compound, and ImmTOR. Pursuant to the Sobi License, in consideration of the license, Sobi agreed to pay the Company a one-time, upfront payment of $75.0 million. Sobi has also agreed to make milestone payments totaling up to $630.0 million to the Company upon the achievement of various development and regulatory milestones and, if commercialized, sales thresholds for annual net sales of NASP, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier. Any proceeds received from milestone payments or royalties relating to the Sobi License would be required to be distributed to holders of CVRs, net of certain deductions.

Pursuant to the Sobi License, the Company agreed to supply (at cost) quantities of the Compound and ImmTOR as necessary for completion of the two Phase 3 clinical trials of NASP (DISSOLVE I and DISSOLVE II) and a six-month placebo extension. The Company was required to supply quantities of the Compound until all rights to the Compound and any materials needed to manufacture the Compound were transferred to Sobi, which transfer occurred upon the execution of Amendment No. 1 to the License and Development Agreement on October 31, 2023. Sobi has agreed to reimburse the Company for all budgeted costs incurred to complete development of NASP, including but not limited to costs incurred while conducting and completing the Phase 3 DISSOLVE trials, except for any costs of additional development activities required that are related to ImmTOR and that are unrelated to NASP. Sobi will have control and responsibility over all regulatory filings, including any investigational drug applications, or IND, biologics license applications, or BLA, and marketing authorization applications, or MAA relating to the licensed product.

The transactions contemplated by the Sobi License were consummated on July 28, 2020. Sobi may terminate the Sobi License for any reason upon 180 days' written notice to the Company, whereby all rights granted under the Sobi License would revert back to the Company. In addition, if Sobi were to terminate the Sobi License, the Company has the option to obtain a license to all patents and know-how necessary to exploit NASP in existence as of the termination date from Sobi in return for making an equitable royalty payment to Sobi.

The Company determined that the Sobi License represents a service arrangement under the scope of ASC 606. In addition, given the Sobi License and Sobi Purchase Agreement were executed contemporaneously and negotiated as a package with a single commercial objective, the Company will account for the two agreements as a single contract. The term of the Sobi License commenced upon the effective date of July 28, 2020 and will continue on a product-by-product basis until the royalty terms for each country have expired. The royalty term for a given product begins upon the first commercial sale of the product in a country and ends at the later of ten years from the first commercial sale, expiration of the last valid patent claim covering the product and expiration of all regulatory exclusivity periods for the product in a country. Given the reversion of the rights under the Sobi License represents a penalty in substance for a termination by Sobi, the contract term would remain the stated term of the Sobi License.

The Company determined that the Sobi License contained three distinct performance obligations due to the nature of the promises in the contract, which includes conducting the Phase 3 DISSOLVE trials, Sobi's option to set-up a second source supplier, and a combined obligation comprised of the delivery of the license to NASP, transfer of the know-how and the manufacturing and delivery of NASP supply for development, or the Combined License Obligation. As the set-up of a second source supplier was optional for Sobi and the Company was to be reimbursed at cost for its efforts in the subsequent set-up and

technology transfer, the option for this future service was determined to be at a significant and incremental discount to its standalone selling price and treated as a material right in the arrangement, namely a distinct performance obligation.

In determining the transaction price, the Company concluded the upfront payment of $75.0 million and the $5.0 million development milestone associated with the dosing of the first patient in the Phase 3 DISSOLVE trials were included in the transaction price. All other development milestones will be fully constrained and only be included in the transaction price when the respective milestone is deemed probable of achievement. Each of these variable consideration items was evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of the evaluation of the constraint, the Company considered numerous factors, including that receipt of such milestones is outside the control of the Company and probability of success criteria is estimated. The Company re-evaluates the transaction price in each reporting period, as uncertain events are resolved. In accordance with ASC 606, the Company will only recognize revenue associated with sales-based milestones and royalties when the subsequent sales thresholds are reached and underlying sales occur, respectively. In connection with the Sobi Purchase Agreement, the Company determined that the gross proceeds of $25.0 million from the Sobi Private Placement included a premium to the fair value of the Company's shares as of July 28, 2020 equal to approximately $14.5 million. The premium amount is included in the transaction price for revenue recognition. The Company estimates and includes in the transaction price the total reimbursements to be received from Sobi for both the manufacturing and delivery of the Compound and ImmTOR as well as conducting the Phase 3 DISSOLVE trials. The Company determined that a significant financing component does not exist in its arrangement with Sobi.

The Company allocated the transaction price based on the relative standalone selling prices of the three distinct performance obligations. The Company estimated the standalone selling price of conducting the Phase 3 DISSOLVE trials by forecasting its anticipated costs and applying a margin reflective of the industry. The Company determined the standalone selling price of the second source supplier option by determining the discount given to Sobi multiplied by the likelihood that Sobi would have exercised the option in the future. Similar to the Phase 3 program estimate, the Company estimated the discount of the option by forecasting the set-up costs and applying a margin that is reflective of the industry. As the Company was to provide the set-up and technology transfer services and the future supply at cost, the discount of the option was equal to the margin amount. The Company considered discussions with Sobi as well as probability of regulatory success of NASP in determining the likelihood of exercise. The Company estimated the standalone selling price of the Combined License Obligation by utilizing a discounted cash flow model.

The Company determined that the delivery of the supply to Sobi best represented the pattern of delivery of the Combined License Obligation as the supply was essential to the utility of the license and know-how. The Company recognized the revenue allocated to the Combined License Obligation by utilizing the output method. The Company estimated the total supply of the Compound and ImmTOR required during the clinical trial period and recognized revenue as this supply was shipped for use in the clinical trials. The Company recognized the revenue allocated to the conducting of the Phase 3 DISSOLVE trials obligation by utilizing the input method. The Company estimated the total budgeted costs to be incurred over the Phase 3 DISSOLVE trials and recognized revenue as these costs were incurred. The Company's costs best represented the pattern of transfer as these captured all performance of the trials completed to date and were readily able to be measured. The Company was to recognize the revenue allocated to the second source supplier option when the future services and goods were transferred.

On June 29, 2022, the Company completed enrollment of the DISSOLVE II trial. The completion of enrollment of the DISSOLVE II trial resulted in the achievement of a development milestone and a $10.0 million payment obligation from Sobi to the Company. This amount was added to the overall transaction price and payment was received during the year ended December 31, 2022.

On October 31, 2023, the Company and Sobi entered into Amendment No. 1 to the License and Development Agreement, pursuant to which the Company granted Sobi an exclusive license to manufacture ImmTOR solely in connection with Sobi's development of NASP under the License and Development Agreement and transferred certain contracts and manufacturing equipment to Sobi. Additionally, Sobi's option to set-up a second source supplier was removed as a result of the amendment. Further, in connection with entry into the amendment, Sobi agreed to make employment offers to certain of the Company's employees engaged in ImmTOR manufacturing activities on or prior to a specified date, and the Company agreed not to terminate the employment of such employees prior to such specified date. The Company maintains no responsibilities to Sobi to manufacture, or supply Sobi with, ImmTOR under the Sobi License.

On June 28, 2024, Sobi initiated a rolling biologics license application to the FDA for NASP for the potential treatment of chronic refractory gout which resulted in the achievement of a development milestone and a $30.0 million payment obligation from Sobi to the Company. As a result, the development milestone was no longer constrained and $30.0 million was recognized as revenue during the year ended December 31, 2024 as there were no remaining performance obligations under the Sobi License. The proceeds from the achievement of the development milestone were received from Sobi in July 2024 and are were included, net of deductions as specified in the CVR Agreement, in the distribution to holders of the CVRs in March 2025.

As of December 31, 2025 and 2024, the Company recorded a total outstanding receivable of $0.1 million, representing billings for the Phase 3 DISSOLVE program that are subject to reimbursement by Sobi. As of December 31, 2025 and 2024, there was no unbilled receivable outstanding. No revenue related to the Sobi License was recognized during the year ended December 31, 2025. Revenue of $31.9 million, inclusive of the $30.0 million development milestone, related to the Sobi License was recognized during the year ended December 31, 2024, and $1.9 million of revenue recognized from performance obligations related to prior periods as a result of the change in transaction price during the year ended December 31, 2024.

Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations represent the transaction price of contracts for which work has not been performed, or has been partially performed. As of December 31, 2025, there were no unsatisfied performance obligations from contracts with customers.

Grant revenue

National Institute of Neurological Disorders and Stroke of the National Institutes of Health

In June 2024, the Company received funding approval from the National Institute of Neurological Disorders and Stroke of the National Institutes of Health, or NINDS, for an award of $1.5 million granted for the budget period, which runs from June 2024 through May 2025. In June 2025, the Company received funding approval from NINDS for an additional award of $1.5 million granted for the budget period June 2025 through May 2026. The funding was provided by NINDS to further the Company's use of RNA-based CAR-T cells to combat autoantibody-associated autoimmune disorders. Grant funding is to be used solely for manufacturing of RNA-based CAR-T cells and analysis of samples to inform mechanism of action. The award period runs through May 31, 2026. The Company will recognize grant revenue when expenses reimbursable under the grant have been incurred.

As of December 31, 2025 and 2024, the Company recorded a receivable of $0.9 million and $0.6 million, respectively, that are subject to reimbursement by NINDS. The Company recognized grant revenue of $2.3 million and $0.6 million during the years ended December 31, 2025 and 2024, respectively.

14. Related-Party Transactions

2024 Securities Purchase Agreement

On July 2, 2024, the Company entered into the 2024 Securities Purchase Agreement with the Purchasers. The Purchasers included (i) Timothy A. Springer, Ph.D., a member of the Company's Board of Directors, (ii) TAS Partners LLC, an affiliate of Dr. Springer, and (iii) Chafen Lu, Ph.D., Dr. Springer's wife (see Note 11 "Equity"). The below issuances and sales to related parties of the Company were made during the year ended December 31, 2024.

Name	Shares of Series B Preferred Stock purchased	Total aggregate purchase price (in thousands)
Timothy A. Springer, Ph.D.	1,636,832	$ 32,737
TAS Partners LLC, affiliate of Timothy A. Springer, Ph.D.	721,361	$ 14,427
Chafen Lu, Ph.D., wife of Timothy A. Springer, Ph.D.	1,307	$ 26

2023 Securities Purchase Agreement

On November 13, 2023, the Company entered into the 2023 Securities Purchase Agreement with (i) Timothy A. Springer, Ph.D., (ii) TAS Partners LLC, and (iii) Seven One Eight Three Four Irrevocable Trust, a trust associated with Murat Kalayoglu, M.D., Ph.D., in which the Company agreed to issue and sell an aggregate of 149,330.115 shares of Series A Preferred Stock for an aggregate purchase price of $60.25 million (see Note 11 "Equity"). The 2023 Private Placement included a delayed settlement mechanism, and as a result, the below issuances and sales to related parties of the Company were made during the year ended December 31, 2024.

Name	Shares of Series A Preferred Stock purchased	Total aggregate purchase price (in thousands)
Timothy A. Springer, Ph.D.	99,140.326	$ 40,000

Exercise of Amended 2019 Warrants

On March 26, 2024, TAS Partners LLC exercised 65,681 Amended 2019 Warrants, paid the per-share exercise price of $43.80 in cash for an aggregate exercise price of $2.9 million, and received 65,681 shares of common stock and 1,970,443 CVRs.

15. Collaboration and License Agreements

Biogen MA, Inc.

On September 8, 2023, the Company entered into a non-exclusive, sublicensable, worldwide, perpetual patent license agreement, or the Biogen Agreement, with Biogen MA, Inc., or Biogen to research, develop, make, use, offer, sell and import products or processes containing or using an engineering T-cell modified with an mRNA comprising, or encoding a protein comprising, certain sequences licensed under the Biogen Agreement for the prevention, treatment, palliation and management of autoimmune diseases and disorders, excluding cancers, neoplastic disorders, and paraneoplastic disorders. The Company is not obligated to pay Biogen any expenses, fees, or royalties.

The Company may terminate the Biogen Agreement for any reason or no reason, and Biogen may terminate the agreement after a notice-and-cure period of 30 days if the Company fails to pay a fee owed to Biogen or for any other material breach of the agreement. The Biogen Agreement will otherwise expire when all claims of all issued patents within the patents and patent applications licensed to the Company under the Biogen Agreement have expired or been finally rendered revoked, invalid or unenforceable by a decision of a court or government agency.

The Biogen Agreement encompasses patents and patent applications in the PCT/US2010/026825 patent family, which was filed March 10, 2010. In general, all patents that issue in this family have an expected expiration date of March 10, 2030, subject to potential patent term adjustments and/or extensions. For the U.S. patents and applications in this family, U.S. Patent 9,034,324 was awarded 677 days of patent term adjustment, which would extend the expiration date of this patent to January 16, 2032, absent any challenges to the patent term. The other issued patent in this family was not awarded any patent term adjustment, so its expected expiration date is March 10, 2030.

National Cancer Institute of the National Institutes of Health

Effective September 16, 2019, the Company entered into a nonexclusive, worldwide license agreement, or the NCI Agreement, with the U.S. Department of Health and Human Services, represented by the National Cancer Institute of the National Institutes of Health, or NCI.

Under the NCI Agreement, the Company was granted a license under certain NCI patents and patent applications designated in the agreement, to make, use, sell, offer and import products and processes within the scope of the patents and applications licensed under the NCI Agreement when developing and manufacturing anti-BCMA CAR-T cell products for the treatment of myasthenia gravis, pemphigus vulgaris, and immune thrombocytopenic purpura according to methods designated in the NCI Agreement.

In connection with the Company's entry into the NCI Agreement, Old Cartesian paid to NCI a one-time $0.1 million license royalty payment. Under the NCI Agreement, the Company is further required to pay NCI a low five-digit annual royalty. The Company must also pay earned royalties on net sales in a low single-digit percentage and pay up to $0.8 million in benchmark royalties upon the Company's achievement of designated benchmarks that are based on the commercial development plan agreed between the parties.

Under the NCI Agreement, the Company must use reasonable commercial efforts to bring licensed products and licensed processes to the point of Practical Application (as defined in the NCI Agreement). Upon the Company's first commercial sale, the Company must use reasonable commercial efforts to make licensed products and licensed processes reasonably accessible to the United States public. After the Company's first commercial sale, the Company must make reasonable quantities of licensed products or materials produced via licensed processes available to patient assistance programs and develop educational materials detailing the licensed products. Unless the Company obtains a waiver from NCI, the Company must have licensed products and licensed processes manufactured substantially in the United States. Prior to the first commercial sale, upon NCI's

request, the Company is obligated to provide NCI with commercially reasonable quantities of licensed products made through licensed processes to be used for in vitro research.

Additionally, the Company must use reasonable commercial efforts to submit a BLA with respect to a licensed product by the fourth quarter of 2026 and make a first commercial sale of a licensed product by the fourth quarter of 2028.

The NCI Agreement terminates upon the expiration of the last to expire of the patent rights licensed thereunder, if not sooner terminated. The NCI Agreement encompasses patents and patent applications in the PCT/US2013/032029 patent family, which was filed March 15, 2013. In general, all patents that issue in this family have an expected expiration of March 15, 2033, subject to potential patent term adjustments and/or extensions. For the U.S. patents and applications in this family, only two patents were awarded patent term adjustments. U.S. Patent 9,765,342 was awarded 297 days of patent term adjustment, which would extend the expiration date of this patent to January 6, 2034, absent any challenges to the patent term. The other patent, U.S. Patent 10,876,123, was awarded three days of patent term adjustment, but this patent is subject to terminal disclaimers filed against other family members, so this patent will not extend beyond the March 15, 2033 date. The other issued patents in this family were not awarded any patent term adjustment, so the expected expiration date for these patents also remains March 15, 2033. There is also a pending patent application which, if issued, will expire on March 15, 2033, but could also be subject to patent term adjustment and to any potential future terminal disclaimers.

NCI has the right to terminate the NCI Agreement, after giving written notice and providing a cure period in accordance with its terms, if the Company is in default of a material obligation. The Company has the unilateral right to terminate the agreement in any country or territory by giving NCI 60 days' written notice. The Company agreed to indemnify NCI against any liability arising out of the Company's, sublicensees' or third-parties' use of the licensed patent rights and licensed products or licensed processes developed in connection with the licensed patent rights.

Genovis AB (publ.)

License Agreement

On October 21, 2021, the Company entered into the Genovis Agreement with Genovis. Under the Genovis Agreement, the Company paid to Genovis an upfront payment in exchange for an exclusive license to the Xork enzyme technology across all therapeutic uses in humans, excluding research, preclinical, diagnostic and other potential non-therapeutic applications of the enzyme. Genovis was eligible to earn from the Company development and sales-based milestones and sublicensing fees. The Genovis Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company was to expense costs related to the Genovis Agreement as incurred until regulatory approval was received in accordance with ASC 730. The Company would have assessed the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, would have amortized these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company was also obligated to pay Genovis tiered royalties of low double digit percentages of worldwide annual net sales of collaboration products which would have been expensed as the commercial sales occurred.

In February 2023, the Company made a $4.0 million payment to Genovis as a result of the sublicense of Xork to Astellas. See Note 13, "Revenue Arrangements" to these consolidated financial statements for further discussion on the Astellas Agreement.

In March 2024, the Company notified Genovis of its intention to terminate the Genovis Agreement, which occurred effective September 13, 2024.

Shenyang Sunshine Pharmaceutical Co., Ltd

In May 2014, the Company entered into a license agreement, or the 3SBio License, with Shenyang Sunshine Pharmaceutical Co., Ltd., or 3SBio. The Company has paid to 3SBio an aggregate of $7.0 million in upfront and milestone-based payments under the 3SBio License as of December 31, 2025. The Company is required to make future payments to 3SBio contingent upon the occurrence of events related to the achievement of clinical and regulatory approval milestones of up to an aggregate of $15.0 million for products containing the Company's ImmTOR platform.

16. Income Taxes

The Company provides for income taxes under ASC 740. Under ASC 740, the Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse.

On November 13, 2023, the Company acquired, in accordance with the terms of the Merger Agreement, the assets of Old Cartesian. In accordance with ASC 805-740-25-3, recognition of deferred tax assets and liabilities is required for substantially all temporary differences and acquired tax carryforwards and credits. The Company does not have a tax basis in IPR&D booked as part of the purchase accounting. For accounting purposes, the IPR&D will not be amortized and only subject to impairment review and testing. Though the tax effects may be delayed indefinitely, ASC 740-10-55-63 states that "deferred tax liabilities may not be eliminated or reduced because a reporting entity may be able to delay the settlement of those liabilities by delaying the events that would cause taxable temporary differences to reverse". The Company can potentially only utilize indefinite-lived assets as it relates to this indefinite lived intangible deferred tax liability reversal. As such, the Company booked a deferred tax liability for the portion of the liability that cannot be reduced based on scheduling through the year ended December 31, 2025.

For the year ended December 31, 2025, the Company recognized a current tax benefit of $9.2 million. For the year ended December 31, 2024, the Company recognized a current tax expense of $0.3 million.

The components of the benefit (expense) for income taxes for the years ended December 31, 2025 and 2024 consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred:		
Federal	$ 571	$ 97
State	8,622	(384)
Total deferred	9,193	(287)
Income tax benefit (expense)	$ 9,193	$ (287)

The following table reconciles the federal statutory income tax rate to the Company's effective income tax rate after applying ASU 2023-09 prospectively for the year ended December 31, 2025 (in thousands, except for percentages):

	Year Ended December 31, 2025	
Expected tax benefit	$ 29,256	21.0 %
Nontaxable or nondeductible items	203	0.1 %
State and local taxes, net of federal benefit	3,206	2.3 %
Effect of changes in tax laws or rates enacted in the current period	3,604	2.6 %
Change in valuation allowance, net	(31,573)	(22.6)%
Tax credits:		
Orphan drug credits	3,959	2.8 %
Research tax credits	892	0.6 %
Other reconciling items:		
Change in fair value of the CVR liability	(714)	(0.5)%
Other	360	0.3 %
Income tax benefit (expense)	$ 9,193	6.6 %

The following table reconciles the federal statutory income tax rate to the Company's effective income tax rate prior to the adoption of ASU 2023-09 for the year ended December 31, 2024:

	Year Ended December 31, 2024
Statutory U.S. federal rate	21.0 %
State income taxes - net of federal benefit	10.5 %
Permanent items	1.0 %
Research tax credits	0.3 %
Change in fair value of the CVR liability	127.9 %
Change in fair value of forward contract liabilities	(1.9)%
Valuation allowance, net	(160.1)%
Stock-based compensation	0.9 %
Effective income tax rate	(0.4)%

The tax effects of temporary differences that give rise to the Company's net deferred tax assets are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred Tax Assets		
Net operating loss carryforwards	$ 60,899	$ 44,062
Research and development credits	10,724	6,024
Stock-based compensation expense	2,601	1,070
Patent and license costs	8,340	8,540
Deferred revenue	80,769	75,567
Operating lease liabilities	3,729	3,848
Contingent value right liability	115,330	108,832
Research & experimental expenditure capitalization	36,820	26,863
Other expenses	588	—
Gross deferred tax assets	$ 319,800	$ 274,806
Deferred Tax Liabilities		
Intangible assets	$ (27,619)	$ (41,441)
Depreciation	(571)	(115)
Operating lease right-of-use assets	(1,648)	(1,523)
Gross deferred tax liabilities	$ (29,838)	$ (43,079)
Net deferred tax assets before valuation allowance	$ 289,962	$ 231,727
Valuation allowance	(296,910)	(247,867)
Net deferred tax liabilities	$ (6,948)	$ (16,140)

The Company has provided a full valuation allowance against its net deferred tax assets, outside of the indefinite tax liability booked as part of the Merger. The Company believes that it is more likely than not that the net deferred tax assets will not be realized.

Realization of future tax benefits is dependent on many factors, including the Company's ability to generate taxable income. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and concluded that it is more likely than not that the Company will not realize the benefit of its net deferred tax assets. The valuation allowance increased by $49.0 million for the year ended December 31, 2025, primarily as a result of tax loss and an increase in research and experimental, or R&E, expenditure capitalization in the current year. The valuation allowance increased by $123.6 million for the year ended December 31, 2024, primarily as a result of tax loss in the current year and a tax benefit determined in the year for the Company's CVR liability.

At December 31, 2025, the Company has federal net operating loss, or NOL, carryforward of $209.0 million, which can be carried forward indefinitely, subject to an 80% limitation and state net operating loss carryforward of $265.2 million, of which $128.6 million has an unlimited carryforward, subject to an 80% limitation, and the remaining $136.6 million will expire at various times through 2045. The Company has $10.0 million and $0.9 million, respectively, of federal and state research and development tax credit carryforwards, which will expire at various times through 2045. Utilization of the NOL carryforwards

and research and orphan drug credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state law due to ownership changes that could occur in the future.

These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. If the Company experiences a change of control, as defined by Section 382 of the Code and similar state law, utilization of the NOL carryforwards or research and orphan drug credit carryforwards may be subject to an annual limitation under Section 382 of the Code, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOL carryforwards or research and orphan drug credit carryforwards before utilization. The Company performed an analysis of ownership changes through December 31, 2023. Based on this analysis, the Company does not believe that any of its tax attributes through December 31, 2023 will expire unutilized due to Section 382 limitations. To the extent the Company enters into future equity transactions, there could be a limitation on the Company's tax attributes.

The Company applies ASC 740, *Income Taxes* to uncertain tax positions. As of the adoption date on January 1, 2010 and through December 31, 2025, the Company had no unrecognized tax benefits or related interest and penalties accrued.

As of December 31, 2025, the Company has not completed a detailed study of its research and development and orphan drug credits for the tax years ending December 31, 2023 through December 31, 2025. As a result, the Company will adjust its deferred tax asset balances and include the impacts in the research tax credits and state income taxes – net of federal benefit lines in the effective rate reconciliation next year, once the updated study has been completed.

On July 4, 2025, the One Big Beautiful Bill Act, or OBBBA, was enacted. The OBBBA amends U.S. tax law including provisions related to domestic R&E expenses and bonus depreciation, among others. The provision related to domestic R&E allows for immediate expensing of domestic R&E costs along with accelerated deductions on previously capitalized domestic R&E costs. The Company has included impacts for the provisions in effect for tax years beginning after December 31, 2024 in its financial statements for the year ending December 31, 2025. The OBBBA had no impact on the Company's current or deferred tax expense as the Company is in a tax loss position and maintains a valuation allowance.

Interest and penalty charges, if any, related to unrecognized tax benefits would be classified within income tax benefit (expense) in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2025, the Company had no accrued interest related to uncertain tax positions.

The statute of limitations for assessment by the Internal Revenue Service and state tax authorities is open for tax years 2020 to the present. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state tax authorities to the extent utilized in a future period. The Company files income tax returns in the United States, Massachusetts, and Maryland. There are currently no federal, state or foreign audits in progress.

17. Employee Benefit Plan

The Company maintains a defined contribution plan, or the 401(k) Plan, under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The 401(k) Plan provides for matching contributions on a portion of participant contributions pursuant to the 401(k) Plan's matching formula. All matching contributions vest ratably over two years and participant contributions vest immediately. Contributions by the Company totaled $0.4 million and $0.2 million during the years ended December 31, 2025 and 2024, respectively.

18. Commitments and Contingencies

As of December 31, 2025, the Company was not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

Other

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at, the Company. Through December 31, 2025, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Additionally, as permitted under Delaware law, the Company indemnifies its directors for certain events or occurrences while the director is, or was, serving at the Company's request in such capacity. The term of the indemnification is for the director's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' insurance coverage that limits its exposure and enables it to recover a portion of any future amounts paid. The Company also has indemnification arrangements under certain of its facility leases that require it to indemnify the landlord against certain costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from certain breaches, violations, or non-performance of any covenant or condition of the Company's lease. The term of the indemnification is for the term of the related lease agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. To date, the Company had not experienced any material losses related to any of its indemnification obligations, and no material claims with respect thereto were outstanding.

The Company is a party in various other contractual disputes and potential claims arising in the ordinary course of business. The Company does not believe that the resolution of these matters will have a material adverse effect the Company's business, financial position, results of operations or cash flows.

19. Restructuring

In April 2023, in light of current market conditions, the Board of Directors took steps to extend the Company's cash runway by pausing further development of the Company's product candidate, SEL-302, for the treatment of methylmalonic acidemia and conducting a targeted headcount reduction. On August 17, 2023, the Company announced additional steps to extend cash runway and maximize value for stockholders by continuing to prioritize development of the Company's product candidate, NASP, and support of its collaboration with Astellas for Xork, and pausing further development of all of the Company's other clinical and preclinical product candidates that it was no longer actively advancing.

As a result of these measures, the Company implemented a restructuring plan that resulted in an approximate 90% reduction of the Company's headcount as of April 2023.

The following table summarizes the change in the Company's accrued restructuring balance included in accrued expenses and other current liabilities on its consolidated balance sheets (in thousands):

	December 31, 2023	Charges	Cash Payments	December 31, 2024
Severance liability	$ 3,896	$ 798	$ (4,614)	$ 80

	December 31, 2024	Charges	Cash Payments	December 31, 2025
Severance liability	$ 80	$ —	$ (80)	$ —

The Company recognized restructuring expenses consisting of one-time cash severance payments and other employee-related costs. The Company recorded these restructuring charges based on each employee's role to the respective research and development and general and administrative operating expense categories on its consolidated statements of operations and comprehensive loss. For the year ended December 31, 2025, the Company recognized no restructuring charges. For the year ended December 31, 2024, the Company recognized $0.2 million in research and development expenses and $0.6 million in general and administrative expenses. Payments for the restructuring plan were completed in the first quarter of 2025.

20. Segment Reporting

Factors used in determining the reportable segment include the nature of the Company's operating activities, the organizational and reporting structure and the type of information reviewed by the CODM to allocate resources and evaluate financial performance. The accounting policies of the segment are the same as those described in Note 2 "Summary of Significant Accounting Policies".

The following table presents selected financial information with respect to the Company's single operating segment for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	**2024**
Revenue:		
Collaboration and license	$ 400	$ 38,275
Grant	2,397	638
Total revenues	2,797	38,913
Less:		
Operating expenses:		
Legacy Selecta programs	—	6,150
Descartes-08 for MG	22,893	12,142
Early stage programs	5,795	1,028
Research and development employee expenses	16,826	11,952
Research and development stock-based compensation expense	4,772	3,217
Research and development facilities and other expenses	7,748	10,616
General and administrative	31,468	30,126
Impairment of indefinite-lived intangible and long-lived assets	56,700	7,579
Other (income) expense, net [(1)]	(13,103)	33,527
Net loss	$ (130,302)	$ (77,424)

[(1)] Includes interest income; gain on change in fair value of warrant liabilities; loss on change in fair value of contingent value right liability; loss on change in fair value of forward contract liabilities; other (expense) income, net and income tax benefit (expense).

21. Subsequent Events

The Company has evaluated subsequent events through the date on which the consolidated financial statements were issued. The Company has concluded that no subsequent events have occurred that require disclosure.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

As of December 31, 2025, Cartesian Therapeutics, Inc. (the "Company," "we," "us" and "our") had two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.0001 per share ("common stock"), and contingent value rights ("CVRs").

The following description of our securities is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our restated certificate of incorporation, as amended (the "Charter"), our amended and restated by-laws (the "Bylaws"), the Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock, as amended (the "Series A Certificate of Designation") governing the Company's Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"), the Certificate of Designation of Preferences, Rights and Limitations of the Series B Non-Voting Convertible Preferred Stock (the "Series B Certificate of Designation") governing the Company's Series B Non-Voting Convertible Preferred Stock, par value $0.0001 per share (the "Series B Preferred Stock"), the Contingent Value Rights Agreement (the "CVR Agreement") by and between the Company and Equiniti Trust Company, LLC (in such capacity, the "Trustee"), dated December 6, 2023, and applicable provisions of the Delaware General Corporation Law ("DGCL"). Our Charter, Bylaws, the Series A Certificate of Designation, the Series B Certificate of Designation, and the CVR Agreement are included as exhibits to the Annual Report on Form 10-K of which this Exhibit 4.12 forms a part. We encourage you to carefully read each of the foregoing documents and the applicable provisions of the DGCL for additional information.

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 360,000,000 shares, comprised of 350,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share ("preferred stock"), of which 134,904.563 shares of preferred stock have been designated as Series A Preferred Stock, 437,927 shares of preferred stock have been designated as Series B Preferred Stock, and 9,427,168.437 shares of preferred stock remain undesignated. As of February 28, 2026, there were 26,509,024 shares of our common stock outstanding, 120,790.402 shares of Series A Preferred Stock outstanding, 437,927 shares of Series B Preferred Stock outstanding, no undesignated shares of preferred stock outstanding, and 177,746,054 CVRs outstanding, and an additional 196,850 CVRs held in nominee accounts and reserved for future distribution to holders of certain warrants to purchase common stock (and to be so distributed if and to the extend such warrants are exercised).

The transfer agent and registrar for our common stock, Series A Preferred Stock, and Series B Preferred Stock is Broadridge Corporate Issuer Solutions, Inc. Broadridge Corporate Issuer Solutions, Inc.'s address is P.O. Box 1342, Brentwood, New York 11717 and its telephone number is (877) 830-4932. Equiniti Trust Company, LLC acts as Trustee for the CVRs. Equiniti Trust Company, LLC's address is Wall Street, Floor 23, New York, New York, 10005, and its telephone number is (800) 937-5449.

Common Stock

Our common stock is listed on the Nasdaq Global Market under the symbol "RNAC." The outstanding shares of our common stock are duly authorized, validly issued, fully paid and nonassessable.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our Charter and Bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least a majority of the voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our Charter.

Rights Upon Liquidation

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock.

Dividend Rights

Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

Other Rights

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

Preferred Stock

Pursuant to our Charter, our board of directors is authorized, without stockholder approval, subject to limitations prescribed by law, to issue up to 10,000,000 shares of preferred stock in one or more series, and by filing a certificate pursuant to the applicable law of the State of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the voting rights, if any, designations, powers, preferences and relative, participating, optional, special and other rights of the shares of each series, and any qualifications, limitations or restrictions thereof. 134,904.563 shares of preferred stock have been designated as Series A Preferred Stock and 437,927 shares of preferred stock have been designated as Series B Preferred Stock.

We will fix the voting rights, designations, preferences and rights of the preferred stock of each series, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to such series. Any description of our securities that we file with the Securities and Exchange Commission (the "Commission") describing any such certification of designation may include:

- the title and stated value;
- the number of shares offered;
- the liquidation preference per share;
- the purchase price per share;
- the dividend rate(s), period(s) and/or payment date(s) or method(s) of calculation for dividends;
- whether dividends are cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- our right, if any, to defer payment of dividends and the maximum length of such deferral period;
- the procedures for auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provision for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock, including the conversion price (or manner of calculation) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price, or how it will be calculated, and the exchange period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;

- restrictions on transfer, sale or other assignment, if any;
- whether interests in the preferred stock will be represented by depositary shares;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon the liquidation, dissolution or winding up of our affairs;
- any limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the class or series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions of the preferred stock.

Our board of directors can also increase or decrease the number of shares of any series of preferred stock, but not below the number of shares of that series then outstanding, without any further vote or action by our stockholders. Our board of directors could authorize the issuance of shares of preferred stock with terms and conditions that could have the effect of discouraging a takeover or other transaction that might involve a premium price for holders of the shares or which holders might believe to be in their best interests. The issuance of preferred stock could adversely affect the voting power, conversion or other rights of holders of common stock and reduce the likelihood that holders of common stock will receive dividend payments and payments upon liquidation. We have no current plan to issue any shares of preferred stock other than the shares of our Series A Preferred Stock and Series B Preferred Stock that have been issued to date.

The laws of the State of Delaware provide that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes to the rights of holders of such preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designations.

Series A Preferred Stock

Conversion. On March 27, 2024, we held a special meeting of stockholders at which our common stockholders approved a proposal (the "Conversion Proposal") to issue shares of common stock upon conversion of shares of Series A Preferred Stock, subject to a beneficial ownership limitation described below.

Prior to the stockholder approval of the Conversion Proposal, the shares of Series A Preferred Stock were not convertible into shares of common stock. Following the stockholder approval of the Conversion Proposal, each share of Series A Preferred Stock automatically converted into 33.333 shares of common stock, subject to the beneficial ownership limitation that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of common stock to the extent that, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (initially set by the holder at a number up to 19.9% and thereafter adjusted, provided that no such adjustment exceeds 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion. Such beneficial ownership limitation does not apply to any holder of Series A Preferred Stock who beneficially owned greater than 19.9% of our common stock immediately prior to our November 2023 merger (the "Merger") with the private company then-known as Cartesian Therapeutics, Inc. ("Old Cartesian").

Each share of Series A Preferred Stock outstanding that was not otherwise automatically converted into common stock as a result of the beneficial ownership limitation shall be convertible at any time at the option of the holder, only to the extent the beneficial ownership limitation does not apply to the shares of Series A Preferred Stock to be converted.

Voting Rights. Except as otherwise required by law (e.g., voting on a change to the authorized shares of Series A Preferred Stock or the rights of such shares as required by the DGCL) and the Series A Certificate of Designation, the Series A Preferred Stock does not have voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock, (b) alter or amend the Series A Certificate of Designation, (c) amend the Charter or other organizational documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (d) issue further shares of Series A Preferred Stock, (e) at any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, consummate either (A) a Fundamental Transaction (as defined in the Certificate of Designation) or (B) any merger or consolidation of the Company or other business combination in which our stockholders immediately before such transaction do not hold at least a

majority of our capital stock immediately after such transaction, (f) amend or fail to comply with, in any manner that would be reasonably likely to prevent, impede or materially delay the conversion (or the stockholder approval thereof), or terminate, any of the stockholder support agreements entered into in connection with the Merger (the "Support Agreements"), or agree to any transfer, sale or disposition of such shares subject to the Support Agreements (except for such transfers, sales or dispositions with respect to which the approval of the Company is not required pursuant to the applicable Support Agreement) or (g) enter into any agreement with respect to any of the foregoing.

Dividends. Holders of Series A Preferred Stock are entitled to receive non-cumulative dividends on shares of Series A Preferred Stock equal, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the common stock.

Liquidation and Dissolution. The Series A Preferred Stock ranks on parity with common stock and the Series B Preferred Stock upon any liquidation, dissolution or winding-up of the Company.

Preemptive Rights. The Series A Preferred Stock does not have preemptive rights.

Transferability. The Series A Certificate of Designation does not contain any restrictions upon the transfer of the Series A Preferred Stock.

Redemption. The Series A Preferred Stock is not redeemable.

Series B Preferred Stock

Conversion. On September 20, 2024, we held a special meeting of stockholders at which our common stockholders approved a proposal (the "Series B Conversion Proposal") to issue shares of common stock upon conversion of shares of Series B Preferred Stock, subject to a beneficial ownership limitation described below.

Prior to the stockholder approval of the Series B Conversion Proposal, the shares of Series B Preferred Stock were not convertible into shares of common stock. Following the stockholder approval of the Series B Conversion Proposal, each share of Series B Preferred Stock automatically converted into one share of common stock, subject to the beneficial ownership limitation that a holder of Series B Preferred Stock is prohibited from converting shares of Series B Preferred Stock into shares of common stock to the extent that, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (initially set by the holder at a number up to 19.9% and thereafter adjusted, provided that no such adjustment exceeds 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion. Such beneficial ownership limitation does not apply to TAS Partners LLC or any of its affiliates.

Each share of Series B Preferred Stock outstanding that was not automatically converted into common stock as a result of the stockholder approval of the Series B Conversion Proposal shall be convertible at any time at the option of the holder, only to the extent the beneficial ownership limitation does not apply to the shares of Series B Preferred Stock to be converted.

Voting Rights. Except as otherwise required by law (e.g., voting on a change to the authorized shares of Series B Preferred Stock or the rights of such shares as required by the DGCL) and the Series B Certificate of Designation, the Series B Preferred Stock does not have voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then-outstanding shares of the Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock, (b) alter or amend the Series B Certificate of Designation, or (c) amend the Charter or other organizational documents in any manner that alters or changes the preferences, rights, privileges, or powers of, or restrictions provided for the benefit of the holders of Series B Preferred Stock.

Dividends. Holders of Series B Preferred Stock are entitled to receive non-cumulative dividends on shares of Series B Preferred Stock equal, on an as-if-converted-to-common-stock basis, and in the same form as dividends paid on shares of the common stock.

Liquidation and Dissolution. The Series B Preferred Stock ranks on parity with common stock and the Series A Preferred Stock upon any liquidation, dissolution or winding-up of the Company.

Preemptive Rights. The Series B Preferred Stock does not have preemptive rights.

Transferability. The Series B Certificate of Designation does not contain any restrictions upon the transfer of the Series B Preferred Stock.

Redemption. The Series B Preferred Stock is not redeemable.

Contingent Value Rights

Each CVR entitles the holder thereof to distributions of the following, pro-rated on a per-CVR basis, during the period ending on the date on which the Royalty Term (as defined in our License and Development Agreement, as amended, with Swedish Orphan Biovitrum AB (publ.) (the "Sobi License")) ends (the "Termination Date"):

(i) 100% of all milestone payments, royalties and other amounts paid to us or our controlled affiliates (the "Company Entities") prior to the Termination Date under the Sobi License or, following certain terminations of the Sobi License, any agreement a Company Entity enters into that provides for the development and commercialization of SEL-212 (a "New Applicable Agreement"); and

(ii) 100% of all cash consideration and the actual liquidation value of any and all non-cash consideration of any kind that is paid to or is actually received by any Company Entity prior to the Termination Date pursuant to an agreement between a Company Entity and any person who is not a Company Entity relating to a sale, license, transfer or other disposition of any transferable asset of the Company Entities existing as of immediately prior to the Merger (a "Disposition") other than those exclusively licensed under the Sobi License or which the Company Entities are required to continue to own in order to comply with the Sobi License (a "Disposition Agreement").

The distributions in respect of the CVRs will be made on a semi-annual basis, and will be subject to a number of deductions, subject to certain exceptions or limitations, including for (A) certain taxes, (B) certain out-of-pocket expenses incurred by the Company Entities, including audit and accounting fees incurred in connection with reporting obligations relating to the CVRs, in respect of its performance of the Sobi License or any New Applicable Agreement, in connection with the entry into a Disposition Agreement and under any Disposition Agreement and performance of the Company Entities' related obligations thereunder, (C) a fixed amount of $750,000 for each Distribution Period (as defined below) to account for general and administrative overhead incurred by the Company Entities, (D) in the case of a distribution that includes payments for certain milestones under clause (ii) above and for the upfront portion, if any, of the consideration payable under a Disposition Agreement (a "Trigger Distribution"), the sum of payments made under any liabilities of the Company Entities arising under real property leases in effect as of immediately prior to the closing (the "Closing") of the Merger ("Lease Liabilities") after the Closing and the aggregate remaining payment obligations under the Lease Liabilities outstanding as of the applicable date of measurement (but subject to a positive adjustment in case amounts held back under this clause (D) exceed the liabilities actually incurred under the Lease Liabilities at the time such a lease expires or is terminated, assigned or subleased), and (E) in the case of a Trigger Distribution, the sum of payments made after the Closing under certain liabilities relating to our Xork product candidate ("Xork Liabilities") after the Closing and the aggregate remaining payment obligations under Xork Liabilities outstanding as of the applicable date of measurement but subject to a positive adjustment in case amounts held back under this clause (E) exceed the liabilities actually incurred under the Xork Liabilities at such time as the development activities with respect to Xork are terminated, transferred or assigned by the Company Entities or otherwise completed in accordance with the development plan set forth in our License and Development Agreement with Audentes Therapeutics, Inc. (the "Astellas Agreement"), when such termination, transfer, assignment or completion occurs.

We will calculate the amount of any payment due on the CVRs for each six-month period from January 1 through June 30 and each six-month period from July 1 through December 31 of each year (each such period, a "Distribution Period"), except that the initial Distribution Period will commence on the date of the CVR Agreement and run through June 30, 2024. Payments on the CVRs will be cumulative and will be payable no later than the close of business on each March 15 (for Distribution Periods that end on December 31) and September 15 (for Distribution Periods that end on June 30), commencing on September 15, 2024 (each such date, a "Distribution Payment Date"), to holders of record of the CVRs as of the close of business on the first day of the month of the applicable Distribution Payment Date. If a Distribution Payment Date is not a business day, payment will be made on the immediately succeeding business day, without the accumulation of additional distributions. If the amount of any per-CVR distribution is less than $0.02, we may elect to defer such distribution until the next Distribution Payment Date when the aggregate per-CVR distribution would be $0.02 or greater.

Under the CVR Agreement, as long as any CVRs are outstanding, we will not: (i) without the affirmative vote of the holders of at least 66 and 2/3% of the then-outstanding CVRs modify in a manner adverse to the CVR holders any provision contained in the CVR Agreement with respect to the termination of the CVR Agreement or the CVRs, or the time for payment and amount of any distribution, or modify in any manner any provision of the CVR Agreement if such modification would reduce the amounts payable in respect of the CVRs or modify any other payment term or payment date, (ii) without the consent of each holder of each outstanding CVR affected thereby, reduce the number of CVRs, or modify any provision referenced in the preceding clause (i) or this clause (ii), except

to increase the percentage of CVR holders from whom consent is required or to provide that certain other provisions of the CVR Agreement cannot be modified or waived without the consent of the holder of each CVR affected thereby, (iii) without the consent of the affirmative vote of the holders of a majority of the then-outstanding CVRs, alter, change, amend, or modify, in each case in any material respect or in any manner adverse to the CVR holders, the Sobi License, the Astellas Agreement, or our Exclusive License Agreement with Genovis AB (publ.), terminate the Sobi License, or sell, license, assign, transfer, enter into any monetization transaction, or otherwise dispose of or otherwise grant or suffer to exist a mortgage, pledge, lien, encumbrance or other security interest on all or a portion of (A) the patents or patent applications licensed under the Sobi License or (B) the Sobi License or any rights to receive any milestone payments, royalties or other amounts under the Sobi License, and (iv) subject to limited exceptions, issue any additional CVRs, other than pursuant to the Agreement and Plan of Merger between us, Old Cartesian, and the merger subsidiary parties thereto to former holders of Selecta's common stock or to holders of warrants to purchase common stock.

Additionally, in the event of certain terminations of the Sobi License at a time when any CVRs are outstanding, we will, and will cause our applicable related entities to, exercise our rights to obtain a "reversion license" and enforce any of our rights under the terminated Sobi License that survive the termination or expiration thereof.

Under the CVR Agreement, the Trustee has, and holders of at least 20% of the CVRs then outstanding may also instruct the Trustee to exercise, certain rights to inspection, audit, and enforcement on behalf of all holders of the CVRs.

CVR holders, solely by virtue of their holding of a CVR, are not entitled to dividends issued by us, do not have voting rights with respect to affairs of our Company, and shall have no rights upon a liquidation of our Company. The CVRs are not convertible or redeemable and do not constitute a debt or obligation of our Company.

The CVRs are transferable but are not expected to be listed on any securities exchange and no transaction involving the CVRs is expected to be registered under the Securities Act of 1933, as amended (the "Securities Act").

Registration Rights

Certain holders of our common stock or their transferees are entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act.

These registration rights are granted pursuant to (i) a registration rights agreement we entered into on July 2, 2024 (the "2024 Registration Rights Agreement"), in connection with the private placement of 3,563,246 shares of our common stock and 2,937,903 shares of Series B Preferred Stock (the "2024 Private Placement"), (ii) a registration rights agreement we entered into on November 13, 2023 (the "2023 Registration Rights Agreement"), in connection with the Merger and the private placement of 149,330.115 shares of Series A Preferred Stock (the "2023 Private Placement"), and (iii) a registration rights agreement we entered into on June 11, 2020 (as amended, the "2020 Registration Rights Agreement"), we entered into in connection with the private placement of 5,416,390 shares of our common stock (the "2020 Private Placement").

2024 Registration Rights Agreement

On July 2, 2024, we entered into the 2024 Registration Rights Agreement with the purchasers party thereto. Pursuant to the 2024 Registration Rights Agreement, we agreed to prepare and file a resale registration statement with the Commission within 30 days of July 3, 2024 and to use our reasonable best efforts to cause this registration statement to be declared effective by the Commission within 90 calendar days of July 3, 2024 (or within 120 calendar days of July 3, 2024 if the Commission reviews the registration statement). We have filed a registration statement in satisfaction of such obligations, and for so long as such registration statement remains effective, the resale shares to which such registration statement relates will no longer constitute restricted securities and may be sold freely in the public markets, subject to lapse on any related contractual restrictions related thereto of any holder party thereto, and subject to any restrictions that may be applicable to any control securities.

We have also agreed, among other things, to indemnify the purchasers party thereto and each of their respective officers, directors, agents, partners, members, managers, stockholders, affiliates, investment advisers and employees, each person who controls any such purchaser party and the officers, directors, partners, members, managers, stockholders, agents, investment advisers and employees of each such controlling person from certain liabilities and pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to our obligations under the 2024 Registration Rights Agreement.

Securities of a holder cease to be registrable securities under the 2024 Registration Rights Agreement upon the earlier to occur of the following: (A) a sale pursuant to a registration statement or Rule 144 under the Securities

Act; and (B) the time such shares become eligible for resale by such holder under Rule 144 without the requirement for the Company to be in compliance with the current public information required by Rule 144(c) and Rule 144(i)(2) and without volume or manner-of-sale restrictions, pursuant to a written opinion letter of counsel for the Company to such effect, addressed, delivered and reasonably acceptable to the Company's transfer agent.

2023 Registration Rights Agreement

In connection with the Merger and the 2023 Private Placement, we entered into the 2023 Registration Rights Agreement, pursuant to which we agreed to prepare and file a resale registration statement with the Commission within 90 calendar days following November 15, 2023, with respect to the shares of common stock underlying the Series A Preferred Stock issued in the 2023 Private Placement and the common stock and shares of common stock underlying the Series A Preferred Stock issued to the signatories to the 2023 Registration Rights Agreement in the Merger. We also agreed to use our commercially reasonable efforts to cause such registration statement to be declared effective by the Commission by March 29, 2024 (or by May 13, 2024 if the Commission reviews the registration statement). The parties to the 2023 Registration Rights Agreement previously waived these registration requirements during the period in which we were not eligible to use Form S-3 to register resales of the registrable securities under the 2023 Registration Rights Agreement, and one signatory to the 2023 Registration Rights Agreement has irrevocably waived such registration requirements. We have filed a registration statement in satisfaction of our remaining obligations under the 2023 Registration Rights Agreement, and for so long as such registration statement remains effective, the resale shares to which such registration statement relates will no longer constitute restricted securities and may be sold freely in the public markets, subject to lapse on any related contractual restrictions related thereto of any holder party thereto, and subject to any restrictions that may be applicable to any control securities.

We also agreed to, among other things, indemnify the holders of common stock and Series A Preferred Stock signatory thereto, their officers, directors, members, employees, partners, managers, stockholders, affiliates, investment advisors and agents under such registration statement from certain liabilities and pay all fees and expenses (excluding any legal fees of the selling holder(s), and any underwriting discounts and selling commissions) incident to our obligations under the 2023 Registration Rights Agreement.

Securities of a holder cease to be registrable securities under the 2023 Registration Rights Agreement upon the earlier to occur of the following: (A) a sale pursuant to a registration statement or Rule 144 under the Securities Act; and (B) the time such shares become eligible for resale by such holder under Rule 144 without the requirement for us to be in compliance with the current public information required thereunder and without volume or manner-of-sale restrictions, pursuant to a written opinion letter of counsel for our Company to such effect, addressed, delivered and reasonably acceptable to our transfer agent.

2020 Registration Rights Agreement

Holders of registrable securities under the 2020 Registration Rights Agreement have registration rights until the earlier of (i) such time as there are no longer any registrable securities held by the purchaser, its affiliates or permitted transferees and (ii) such time as all of the securities can otherwise be sold without regard to the volume or manner-of-sale restrictions pursuant to Rule 144. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Piggyback Registration Rights. Any time we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities are entitled to notice of the registration and to include their shares of registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

Demand Registration Rights. If the holders of registrable securities request in writing that we effect a registration with respect to all of the registrable securities, we will be required to effect such registration.

Expenses. Ordinarily, other than underwriting discounts and commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling security holders and blue sky fees and expenses.

Termination of Registration Rights. The registration rights terminate upon the earlier of (i) such time as there are no longer any registrable securities held by the purchaser, its affiliates or permitted transferees and (ii) such

time as all of the securities can otherwise be sold without regard to the volume or manner-of-sale restrictions pursuant to Rule 144.

Anti-Takeover Effects of Delaware Law and Our Charter and Bylaws

Some provisions of the DGCL, our Charter and our Bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interest, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock. The ability of our board of directors, without action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to effect a change in control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our Company.

Stockholder Meetings. Our Bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals. Our Bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent. Our Charter eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board. Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors. Our Charter provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of common stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting. Our Charter does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute. We are subject to Section 203 of the DGCL, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this law may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum. Our Charter provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the DGCL or our Charter or Bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine. Our Charter also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our Charter is inapplicable or unenforceable if it is challenged in a proceeding or otherwise. Investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder and Section 22 of the Securities Act generally creates concurrent jurisdiction for the state and federal courts over suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Amendment of Charter. The amendment of any of the above provisions in our Charter, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of the DGCL, our Charter and our Bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board of directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interest.

Exhibit 10.22

Separation Agreement and Release

This Separation Agreement and Release ("Agreement") is made by and between Christopher Jewell ("Executive") and Cartesian Therapeutics, Inc. (the "Company") (collectively referred to as the "Parties" or individually referred to as a "Party"). Capitalized terms used but not defined in this Agreement shall have the meanings set forth in the Employment Agreement (as defined below).

WHEREAS, the Parties have previously entered into that certain Employment Agreement, dated as of March 26, 2024 (the "Employment Agreement"); and

WHEREAS, in connection with Executive's termination of employment with the Company or a subsidiary or affiliate of the Company effective November 14, 2025, or an earlier date as determined by the Company as described in Section 1 of this Agreement (the "Separation Date"), the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company or its subsidiaries or affiliates but, for the avoidance of doubt, nothing herein will be deemed to release any rights or remedies in connection with Executive's ownership of vested equity securities of the Company, vested benefits or Executive's right to defense or indemnification by the Company or any of its affiliates pursuant to contract or applicable law (collectively, the "Retained Claims"). The Company agrees not to contest Executive's application for unemployment benefits following the Separation Date; provided that nothing herein shall prohibit the Company from responding truthfully to requests for information from, or require the Company to make any false or misleading statements to, any governmental authority; and

WHEREAS, the Company provided Executive with a written Notice of Termination on October 15, 2025 and presented Executive with this Separation Agreement and Release on October 15, 2025.

NOW, THEREFORE, in consideration of the severance payments and benefits described in Section 4 of the Employment Agreement, which, pursuant to the Employment Agreement, are conditioned on Executive's execution and non-revocation of this Agreement, and in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

1. Separation Date; Notice Period. Executive's last day of employment with the Company will be November 14, 2025, unless earlier terminated by the Company with or without Cause (as defined in Section 7(a) of the Employment Agreement), although Executive shall only perform job duties for the Company until October 31, 2025, with the exception of any limited duties subject to any separately executed consulting agreement, which Executive may perform after October 31, 2025. During the period between October 15, 2025 and October 31, 2025 (the "Notice Period"), Executive shall continue to perform their job duties, assist with the transition of their job duties, and abide by the terms of their Employment Agreement, Restrictive Covenants Agreement, and all Company policies. If Executive's employment is terminated by the Company before November 14, 2025 for Cause, Executive will solely be paid their base salary and benefits through the termination date and is not entitled to the Severance Payments described in Section 2 of this Agreement or any other severance from Company. The Company reserves the right to shorten the Notice Period at its

discretion; provided, that, so long as Executive is not earlier terminated for Cause, Executive will be paid at Executive's current base salary and benefits through at least November 14, 2025.

2. Severance Payments; Salary and Benefits. The Company agrees to provide Executive with the severance payments and benefits described in Section 4(b) of the Employment Agreement (the "Severance Payments"), payable at the times set forth in, and subject to the terms and conditions of, the Employment Agreement. In addition, to the extent not already paid, and subject to the terms and conditions of the Employment Agreement, the Company shall pay or provide to Executive all other payments or benefits described in Section 3(c) of the Employment Agreement, subject to and in accordance with the terms thereof. For the avoidance of doubt, if Executive does not sign this Agreement, or Executive signs but then revokes the Agreement, then Executive shall not be entitled to the Severance Payments.

3. Release of Claims. Executive agrees that, other than with respect to the Retained Claims, the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive by the Company, any of its direct or indirect subsidiaries and affiliates, and any of their current and former officers, directors, equity holders, managers, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, insurers, trustees, divisions, and subsidiaries and predecessor and successor corporations and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of any of Executive's affiliated companies or entities and any of their respective heirs, family members, executors, agents, and assigns, other than with respect to the Retained Claims, hereby and forever releases the Releasees from any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the Effective Date of this Agreement (as defined in Section 7 below), including, without limitation:

(a) any and all claims relating to or arising from Executive's employment or service relationship with the Company or any of its direct or indirect subsidiaries or affiliates and the termination of that relationship;

(b) any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of any shares of stock or other equity interests of the Company or any of its affiliates, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;

(c) any and all claims for wrongful discharge of employment; termination in violation of public policy; discrimination; harassment; retaliation; breach of contract, both express and implied; breach of covenant of good faith and fair dealing, both express and implied; promissory estoppel; negligent or intentional infliction of emotional distress; fraud; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; unfair business practices; defamation; libel; slander; negligence; personal injury; assault; battery; invasion of privacy; false imprisonment; conversion; and disability benefits;

(d) any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964; the Civil Rights Act of 1991; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Equal Pay Act; the Fair Credit Reporting Act; the Age Discrimination in Employment Act of 1967; the Older Workers Benefit Protection Act; the Employee Retirement Income Security Act of 1974; the Worker Adjustment and Retraining Notification Act; the Family and Medical Leave Act; the Sarbanes-Oxley Act of 2002; the Maryland Fair Employment Practices Act; the Maryland False Claims Act; the Maryland Parental Leave Act; and the Maryland Healthy Working Families Act.

(e) any and all claims for violation of the federal or any state constitution;

(f) any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

(g) any claim for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement;

(h) any and all claims arising out of the wage and hour and wage payments laws and regulations of the state or states in which Executive has provided service to the Company or any of its affiliates; and

(i) any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not release claims that cannot be released as a matter of law, including, but not limited to, Executive's right to report possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation, Executive's right to file a charge with or participate in a charge, investigation or proceeding by the Equal Employment Opportunity Commission, or any other local, state, or federal administrative body or government agency that is authorized to enforce or administer laws related to employment, against the Company (with the understanding that Executive's release of claims herein bars Executive from recovering monetary or other individual relief from the Company or any Releasee in connection with any charge, investigation or proceeding, or any related complaint or lawsuit, filed by Executive or by anyone else on Executive's behalf before the federal Equal Employment Opportunity Commission or a comparable state or local agency), claims for unemployment compensation or any state disability insurance benefits pursuant to the terms of applicable state law, claims to continued participation in certain of the Company's group benefit plans pursuant to the terms and conditions of COBRA, claims to any benefit entitlements vested as the date of separation of Executive's employment, pursuant to written terms of any employee benefit plan of the Company or its affiliates and Executive's right under applicable law and any Retained

Claims. This release further does not release claims for breach of Section 3(c), Section 4(b) or Section 4(c) of the Employment Agreement arising after the Effective Date.

4. Acknowledgment of Waiver of Claims under ADEA. Executive understands and acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive understands and agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive executes this Agreement. Executive understands and acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further understands and acknowledges that Executive is hereby advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has 21 days within which to consider this Agreement, and the parties agree that such time period to review this Agreement shall not be extended upon any material or immaterial changes to this Agreement unless required by law; (c) Executive has 7 days following Executive's execution of this Agreement to revoke this Agreement pursuant to written notice to the General Counsel of the Company; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21 day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement.

5. Restrictive Covenants.

(a) Executive acknowledges and agrees that the restrictive covenants and other post-termination obligations set forth in the Restrictive Covenant Agreement, including without limitation Executive's obligations relating to confidentiality, non-use and non-disclosure of Confidential Information (as defined in the Restrictive Covenant Agreement), non-solicitation, cooperation, and return of property, are hereby incorporated by reference and shall remain in full force and effect pursuant to their terms to the maximum extent permitted by applicable law. Executive represents and warrants that Executive has complied with all provisions of the Restrictive Covenant Agreement at all times through the Effective Date. For the avoidance of doubt, the Company agrees not to enforce the non-competition provision of the Restrictive Covenant Agreement following the Separation Date.

6. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

7. No Oral Modification; Entire Agreement. This Agreement may only be amended in a writing signed by Executive and a duly authorized officer of the Company. This Agreement sets forth the entire agreement between the Company and Executive, and fully replaces any and

all prior agreements or understandings, written or oral, between Executive and the Company pertaining to the subject matter of this Agreement, except for the provisions of the Employment Agreement incorporated herein by reference and the Restrictive Covenant Agreement, as modified herein, which shall remain in full force and effect.

8. Governing Law. This Agreement shall be subject to the provisions of Sections 9(a) and 9(c) of the Employment Agreement.

9. Effective Date. This Agreement will become effective on the eighth day after Executive signs this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date"). Executive must not execute this Separation Agreement until Executive's last day of employment with the Company. If Executive executes this Separation Agreement before the last day of employment with the Company, the Agreement will not be effective unless Executive timely re-executes the Agreement within twenty-one (21) days following Executive's last day of employment, and then does not revoke the Agreement. For the avoidance of doubt, if Executive's employment is terminated for Cause, then Executive shall not be entitled to the Severance Payments.

10. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily, without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that: (a) Executive has read this Agreement; (b) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement; (c) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel; (d) Executive understands the terms and consequences of this Agreement and of the releases it contains; and (e) Executive is fully aware of the legal and binding effect of this Agreement.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

EXECUTIVE

Dated: 10/20/2025

/s/ Christopher Jewell
Christopher Jewell

CARTESIAN THERAPEUTICS, INC.

Dated: 10/20/2025

By: /s/ Carsten Brunn
Name: Carsten Brunn
Title: CEO

CARTESIAN THERAPEUTICS, INC.

INSIDER TRADING POLICY

I. PURPOSE

Cartesian Therapeutics, Inc. ("Cartesian" or the "Company") has adopted the following policies and procedures with respect to trading in Cartesian securities by members of Company's board of directors, officers and employees. These policies and procedures are designed to help you comply with insider trading laws, handle confidential information properly and avoid potentially embarrassing public disclosures and the appearance of impropriety. You are receiving this policy because you are a Cartesian officer, director or employee, or an external contractor or consultant who has or may have access to material nonpublic information, and are subject to this policy.

All directors, officers and employees, and external contractors and consultants who have access to material nonpublic information, are responsible for reading these policies and procedures and complying with them. Further, even after you are no longer employed by or affiliated with Cartesian, you must maintain the confidentiality of any confidential or proprietary information obtained during your employment or affiliation with Cartesian.

Penalties for violating these policies and procedures may involve any appropriate remedy, including termination of employment. In addition, the Securities and Exchange Commission (the "SEC") and criminal prosecutors vigorously enforce insider trading laws. Violation of insider trading laws could result in civil and criminal penalties under applicable federal securities laws.

If you have any questions about the application of these policies and procedures, or if you would like to make a request for an exception, please contact the General Counsel. Although the Chief Executive Officer, Chief Financial Officer and General Counsel generally are responsible for the implementation of these policies and procedures, the Company's board of directors may designate employees to carry out any of the duties described below.

II. PERSONS COVERED

This policy applies to all (i) directors, officers, employees (permanent or temporary, salaried or hourly) and (ii) external contractors and consultants who have access to material nonpublic information, of Cartesian and its subsidiaries, both inside and outside the United States (collectively, "covered persons"). This policy also applies to all immediate family members of covered persons, any other members of the covered person's family, and other household members (other than tenants and household employees) of covered persons (collectively, "family members"). This policy further applies to all corporations, limited liability companies, partnerships, trusts or other entities controlled by covered persons or family members.

III. COVERED TRANSACTIONS

This policy applies to all transactions in all Cartesian securities, which may include common stock, preferred stock, debt securities, warrants or options to acquire common stock, derivative securities, units or any other type of securities that the Company may issue. This policy also applies to securities of other companies about which you learn material nonpublic information during the course of your relationship with Cartesian.

IV. POLICY AGAINST INSIDER TRADING

A. General Prohibition Against Insider Trading

Federal and state laws prohibit "insider trading," the purchase or sale of securities, in breach of a fiduciary duty or other relationship of trust and confidence, on the basis of material nonpublic information about the security. Any covered person, or any other person designated by this policy, who has material nonpublic information relating to Cartesian may not, until the information becomes public or is no longer material:

- engage in transactions in Cartesian securities, directly or indirectly, except as specifically noted herein;
- recommend the purchase or sale of any Cartesian securities;
- engage in any other action to take personal advantage of that information, including but not limited to, passing on or "tipping" that information to someone who uses it for personal gain, regardless of the quantity of securities traded;
- disclose material nonpublic information to persons within Cartesian whose jobs do not require them to have that information, or outside of Cartesian to other persons, including, but not limited to family, friends, business associates, investors and expert consulting firms, unless any such disclosure is made in express accordance with Cartesian's policies regarding the protection or authorized external disclosure of information concerning the Company; or
- assist anyone engaged in the above activities.

Tipping arises when a covered person discloses material nonpublic information about Cartesian or another publicly-traded entity to another person or recommends another person to trade in the securities of a company while in possession of material nonpublic information about that company, and that person either (i) trades in a security of the company in respect of which you provided information or (ii) provides the information to a third person who then makes a trade in a related security. Tipping is illegal even if you do not personally make a trade or otherwise benefit from disclosing the information.

In addition, any covered person who learns of material nonpublic information about another entity, including an entity with whom Cartesian does business, may not trade in that entity's securities until the information becomes public.

Although you may believe it is necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) to engage in a transaction involving Cartesian's securities, there are no exceptions to this policy's prohibition against insider trading. Even the appearance of impropriety must be avoided to preserve Cartesian's reputation for adhering to the highest standards of conduct.

To ensure compliance with this policy, all covered persons must protect the confidentiality of material nonpublic information, by, for example, avoiding casual conversations about such information in public areas and storing files containing material nonpublic information in secure locations. This policy also covers communications and postings made through the Internet. You must not post any nonpublic or confidential information on the Internet, including through chatrooms, discussion groups, or social media platforms. This includes anonymous posts or discussion on the Internet.

Because insider trading law is complex, you should contact the General Counsel if you have any questions about whether information in your possession is material or nonpublic or if a proposed transaction or communication would violate the insider trading laws. You must also report any unauthorized disclosure of material nonpublic information, whether inadvertent or otherwise, immediately to the Chief Executive Officer, Chief Financial Officer and General Counsel.

B. What Information is "Material"?

For the purposes of these policies and procedures, information is "material" if a reasonable investor would consider that information important in making a decision to trade securities. It is also information that, if disclosed, is reasonably likely to affect the market price of Cartesian's securities. Both positive and negative information can be material. Further, courts and the SEC have declined to identify all information that could be deemed to be material.

Some examples of material information include:

- quarterly or annual earnings information and guidance, including estimates or revisions;
- discussions, proposals or agreements for a significant merger, acquisition or divestiture;
- threatened litigation or administrative actions, or material developments in such matters;
- significant new or prospective contracts, licensing or collaboration agreements;

- significant developments or announcements involving the U.S. Food and Drug Administration and any Cartesian products, product candidates, regulatory applications, or clinical trials;
- significant changes in marketing, pricing strategies or market share;
- significant research and development initiatives, clinical studies, clinical data or new product prospects;
- changes in business strategies;
- changes in key members of management;
- a significant cybersecurity breach or incident;
- changes in debt ratings; and
- stock splits or changes in dividend policies.

The foregoing list does not include all of the information that could be deemed to be material.

C. What Information is "Nonpublic"?

Information is "nonpublic" if it has not been widely disseminated to the public, such as through a press release carried over a major news service, a public filing with the SEC or materials sent to stockholders (e.g., a proxy statement or widely disseminated prospectus). Information is also nonpublic if it has been widely disseminated to the public, but sufficient time has not elapsed to permit the investment community to absorb and evaluate the information. In general, two full business days after public release is deemed sufficient for investor absorption and evaluation.

The distribution of information through narrower channels may be insufficient to make it public. For example, merely posting information on a website may not satisfy the "widely disseminated" standard to make such information public. Also, the fact that nonpublic information is reflected in rumors in the marketplace does not mean that the information has been publicly disseminated. It is important to note that even after information becomes public, many aspects relating to a matter may remain nonpublic.

V. RULES FOR SPECIFIC TRANSACTIONS

In addition to the general prohibition on insider trading described above, certain specific transaction types and related activities are prohibited by this policy.

A. Participation in Expert Networks or Similar Consulting Arrangements

You are not permitted to provide information or services about or relating to Cartesian to "expert network firms" or similar consulting firms. Expert network firms may seek to engage you as a consultant due to your knowledge of Cartesian, or your knowledge of our industry overall. Your provision of such consulting services creates the risk that you may use or disclose, deliberately or inadvertently, Cartesian's confidential information or engage, or assist another party in engaging, in activities that are detrimental to or competitive with the Company. Such activity may also violate federal securities laws. Accordingly, participation in such organizations is strictly prohibited.

B. Derivatives Transactions

You may not engage in derivative transactions involving Cartesian's securities. Derivative transactions are speculative transactions that permit a person to leverage his or her investment using a relatively small amount of money. Transactions in options (other than stock options issued by Cartesian) may create the appearance that a covered person is trading based on material nonpublic information and may focus a covered person's attention on Cartesian's short-term performance. Examples of derivative transactions include, but are not limited to, purchases and sales of put and call options.

C. Hedging, Pledging and Lending

You are prohibited from hedging and lending Cartesian securities in any transaction, including by entering into any short sales, swaps, options, puts, calls, forward contracts or any other similar derivatives transaction. Unless authorized in advance by the Company's board of directors, you are prohibited from pledging Cartesian securities in any transaction.

D. Short Sales

You may not engage in short selling of Cartesian securities. Selling short includes transactions in which you borrow securities from a broker, sell them, and eventually buy securities on the market to cover the number of securities borrowed from the broker. Profit is made if the price of the securities decreases during the period of borrowing. Short sales may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects.

E. Margin Accounts

You may not engage in purchasing Cartesian securities on margin. Purchasing Cartesian securities on margin involves the use of borrowed money from a brokerage firm to purchase the securities. Holding Cartesian securities in a margin account means that the securities can be sold to pay a loan to the brokerage firm. Covered persons are prohibited from holding Cartesian securities in a margin account because a margin sale might occur at a time when the covered person is aware of material nonpublic information.

F. Post-Termination Transactions

You may not engage in trading in Cartesian securities while in the possession of material nonpublic information after your relationship with the Company has ended. This policy continues to apply to transactions in Cartesian securities even after termination of service to Cartesian. If an individual is in possession of material non-public information when his or her service terminates, that individual may not trade in Cartesian securities until that information has become public or is no longer material.

VI. WHEN TRADING IS GENERALLY PERMITTED

To help directors, officers and employees conduct trades in Cartesian securities in compliance with the general prohibition described above, Cartesian has established mechanisms for effecting trades in the Company's securities in compliance with these policies and procedures. If you are not certain whether a proposed transaction complies with the mechanisms described below, you should contact the General Counsel.

A. Window Periods

The Company requires that covered persons limit their trading in Company securities to prescribed "Window Periods." The periods between Window Periods are considered "Blackout Periods". Covered persons may not engage in trades in Company securities during Blackout Periods. The requirement to make trades during a Window Period does not apply to transactions described below under the headings "Rule 10b5-1 Plan Trading," "Option Exercises," "Estate Planning and Gifts," "Employee Stock Purchase Plans," "Tax Obligations" and "Transactions with the Company."

Under this policy, a Window Period begins at market opening on the third business day after the Company has issued its usual press release announcing quarterly results and ends three calendar days prior to the end of the applicable fiscal quarter. The Company retains the discretion to close a Window Period in the event of any major corporate development that has not been announced to the public. The closing of any Window Period will be announced by email. If you think you have any material nonpublic information during the Window Period, however, you must consult the General Counsel before trading Cartesian securities.

Cartesian also strongly encourages employees, family members and close associates of any officer, employee or member of the board of directors to confine their trading in Cartesian securities to a Window Period. While there is no violation of insider trading rules if it can be shown that a family member or other person associated with a director, officer or employee acted independently when trading and without knowledge of material nonpublic information, a strong presumption may arise that material nonpublic information has been shared with such person by the officer, employee or member of the board of directors.

B. Special Blackout Periods

The Company may impose special periods during which certain covered persons will be prohibited from trading or otherwise effecting transactions in Cartesian securities ("special blackout periods") even though the Window Period would otherwise be open. This would be

the case, for example, for Company employees working on a material merger or acquisition transaction, or another event that could involve material nonpublic information. If a special blackout period is imposed, the Company will notify affected individuals by email. The Company will also notify affected individuals at the end of such special blackout period.

Please note that special blackout periods may apply to all individuals working on material transactions or other matters that could involve material nonpublic information, even if those individuals only have a limited role in the transaction. A special blackout period for these matters is not necessarily limited to individuals who are on any particular team or function. The determination of whether a project or transaction is material will be made by the Chief Executive Officer, Chief Financial Officer and General Counsel.

C. Rule 10b5-1 Plan Trading

To avoid liability for insider trading, officers and members of the board of directors may wish to rely upon the affirmative defenses established by Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Rule 10b5-1 is available to an individual or entity who purchases or sells a security under a binding contract, specific instruction or written plan that the person or entity put into place before becoming aware of material nonpublic information (such a written plan, a "Rule 10b5-1 plan"). If the trading plan meets all of the requirements of Rule 10b5-1, Cartesian securities may be purchased and sold under such plan without regard to certain insider trading considerations, and such trades would not be restricted to the window periods under this policy.

The Company strongly encourages any of the following covered persons who wish to trade in Cartesian securities to limit such trading activity to Rule 10b5-1 plans adopted in accordance with this policy: (i) members of the board of directors and (ii) officers appointed by the board of directors. In addition, other covered persons who wish to trade in Cartesian securities may be encouraged to limit their trading activity to Rule 10b5-1 plans adopted in accordance with this policy, based on the determination of the Chief Executive Officer, Chief Financial Officer or General Counsel.

A covered person who enters into a Rule 10b5-1 plan is strongly discouraged from trading in any securities of the Company outside of the Rule 10b5-1 plan.

To create a Rule 10b5-1 plan, you must enter into a written plan for trading securities that must:

- specify the amount, price and date of the transaction(s);
- include a written formula, algorithm or computer program for determining the amount, price and date of the transaction(s); or
- not permit the person for whom shares are being purchased or sold to exercise any subsequent influence over how, when or whether to effect purchases or sales, while

at the same time ensuring that the person effecting the trades is not aware of any material nonpublic information at the time of the trades.

In order to rely on the defense, a person must adopt a Rule 10b5-1 plan that meets all of the rule's requirements. These include a requirement that the plan include a representation certifying that the person adopting the plan is doing so in good faith, at a time when he or she is not in possession of material nonpublic information and not as part of a plan to evade the insider trading prohibitions. Additionally, a director or officer adopting a new Rule 10b5-1 plan may not have any other outstanding Rule 10b5-1 plan, and may not subsequently enter into any additional Rule 10b5-1 plan, subject to certain exceptions. Frequent amendment of, or deviation from, a trading plan may make it difficult for an insider to demonstrate that he or she has satisfied the rule's "good faith" requirement.

A Rule 10b5-1 plan must provide for a "cooling off" period before purchases and sales can occur under the plan. For a director or officer, no purchases or sales under the Rule 10b5-1 plan can occur until the later of (i) 90 days after the adoption of the Rule 10b5-1 plan and (ii) two business days following disclosure of the Company's results in a Form 10-Q or Form 10-K for a completed fiscal quarter in which the plan was adopted; provided, however, that in no event will the required cooling off period be longer than 120 days after adoption of the Rule 10b5-1 plan. No purchases or sales under a Rule 10b5-1 plan for a person other than a director or officer may be made until 30 days after adoption of the plan.

Any modification to the amount, pricing, or timing of purchases or sales of securities under a Rule 10b5-1 plan will constitute the termination of the plan and adoption of a new plan, which means that any such modification will trigger the need for the new trading plan to satisfy all of the elements of Rule 10b5-1, including a new cooling off period before trading can begin again.

Stock brokerage firms may assist directors, officers and employees in establishing Rule 10b5-1 plans. To ensure that such arrangements comply with Rule 10b5-1, Cartesian requires that any covered person who wishes to establish a Rule 10b5-1 plan:

- enter into the required contract, provide the required instructions, or adopt the required plan, during a Window Period and otherwise while not in possession of material nonpublic information;
- obtain prior approval from the Chief Executive Officer, Chief Financial Officer or General Counsel for such Rule 10b5-1 plan, as well as any amendment of such plan;
- report promptly to the Chief Executive Officer, Chief Financial Officer and General Counsel all transactions made pursuant to the Rule 10b5-1 plan, as well as any termination of the plan; and
- adopt a plan with a duration of at least six months.

D. Options Exercises

Directors, officers and employees who have stock options or other rights granted by Cartesian to purchase securities from the Company may exercise the options or purchase rights at any time permitted under the terms of the applicable option or other agreement so long as the exercise does not involve a broker-assisted cashless exercise. This rule applies only to options or purchase rights granted by the Company. Rules pertaining to options or purchase rights granted by third parties are described in the sections above captioned "Derivatives Transactions," "Short Sales" and "Margin Accounts." Please be aware, however, that any subsequent sale of securities purchased by means of the exercise of stock options or other rights in accordance with this policy must be made during a Window Period, pursuant to a Rule 10b5-1 plan, or otherwise approved by the Chief Executive Officer, Chief Financial Officer or General Counsel.

E. Estate Planning and Gifts

Directors, officers and employees may at any time make bona fide gifts of Cartesian securities (such as charitable donations or family gifts or estate planning transfers). Depending on the circumstances, recipients of gifts may be subject to restrictions on subsequent sales of securities. Any such gifts made by directors and officers subject to Section 16 of the Exchange Act must be reported on Form 4 within two business days of the date of the transaction.

Gifts that are part of a plan to circumvent the insider trading rules are not permitted.

F. Employee Stock Purchase Plans

Purchases of Cartesian stock under the Company's employee stock purchase plan, if any, resulting from periodic or lump sum contributions of money thereto, pursuant to an election made at the time of plan enrollment, are not subject to this policy. Your initial election to participate in the plan, changes to that election for any enrollment period and sales of Cartesian stock purchased pursuant to the plan *are* subject to this policy and must comply therewith.

G. Tax Obligations

Transactions between covered persons and Cartesian that are undertaken to satisfy tax obligations, such as upon the vesting of restricted stock units and the net issuance of shares, which effectively involves disposing of vested shares to the Company, are exempt under this policy.

H. Transactions with the Company

Purchases of Cartesian securities by a covered person from the Company, or sales of the Company's securities by a covered person to the Company, may be made outside a Window Period with the prior approval of the Chief Executive Officer, Chief Financial Officer or General Counsel.

VII. PRE-CLEARANCE PROCEDURES

The following Company personnel may not trade or engage in any other transaction involving the Company's securities (including a securities plan transaction such as an option exercise, a gift, a loan or pledge, a contribution to a trust or any other transfer) without first obtaining pre-clearance of the transaction from the Chief Executive Officer, Chief Financial Officer or General Counsel:

- all directors and executive officers who trade outside of a Rule 10b5-1 plan entered into in accordance with this policy;
- key financial or investor relations employees as designated by the Chief Executive Officer, Chief Financial Officer or General Counsel; and
- all such other individuals as designated by the Chief Executive Officer, Chief Financial Officer or General Counsel.

This pre-clearance requirement applies regardless of whether (i) the individual subject to pre-clearance possesses material nonpublic information regarding the Company or its securities or (ii) the trade occurs during a Window Period.

A request for pre-clearance must be submitted to the Chief Executive Officer, Chief Financial Officer and General Counsel at least two business days prior to consummation of an intended transaction; provided, however, that none of the Chief Executive Officer, Chief Financial Officer or General Counsel may provide pre-clearance for a proposed transaction by him or herself. Notice may be given orally or in writing and should include in the request (i) the transaction type, (ii) the number and type of securities he or she intends to trade, (iii) the intended transaction date, (iv) a confirmation that he or she has reviewed this policy and (v) a confirmation that he or she is not aware of any material nonpublic information about the Company or its securities. Approval or denial of the pre-clearance request will be provided to the insider in writing.

If a proposed transaction receives pre-clearance, the pre-cleared trade must be effected by the close of business on the second business day following receipt of pre-clearance unless (i) the insider becomes aware of material nonpublic information or (ii) the insider is advised by the Company that the pre-clearance has been revoked prior to that time. In the case of either (i) or (ii), the trade must not be completed. For example, if the pre-clearance were issued on a Friday, it would generally be effective through the close of business on the next Tuesday. If the transaction order is not placed within this time period, clearance of the transaction must be re-requested. Notice of a pre-cleared transaction must be provided by the applicable insider to the Chief Executive Officer, Chief Financial Officer and General Counsel on the same date of execution. Please note that the date of execution is the trade date and not the settlement date.

VIII. SECTION 16 POLICY

Covered persons who are Company directors and officers subject to Section 16 of the Exchange Act must follow the additional policies and procedures set forth in Annex A to this policy.

IX. INQUIRIES

Any person who has a question about this policy or its application to any proposed transaction may obtain additional guidance from the General Counsel, who can be reached by email at matt.bartholomae@cartesiantx.com.

Adopted on March 20, 2024.

ANNEX A

ADDITIONAL POLICIES AND PROCEDURES ON TRADING CARTESIAN SECURITIES BY COMPANY DIRECTORS AND OFFICERS

I. INTRODUCTION

Cartesian, Inc. ("Cartesian" or the "Company") has adopted the following policies and procedures with respect to trading in Cartesian securities by the Company's directors and officers. These policies and procedures supplement the Cartesian Insider Trading Policy and are designed to help directors and officers comply with the requirements of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

All persons subject to this policy are responsible for reading these policies and procedures and complying with them. You should direct any questions about the application of these policies and procedures or requests for exceptions, to the General Counsel. Although the Chief Executive Officer, Chief Financial Officer and General Counsel generally are responsible for the implementation of these policies and procedures, the Chief Executive Officer, Chief Financial Officer or General Counsel may designate employees to carry out any of the duties described below.

II. PERSONS AFFECTED

This policy applies to Cartesian's directors and officers. Cartesian's board of directors has designated "officers" for purposes of Section 16, each of whom will be subject to the reporting requirements and "short-swing" profit provisions of Section 16 discussed below. If you are a director of Cartesian or have been designated as an "officer" of Cartesian for the purposes of Section 16, you should read this Annex carefully.

III. REPORTING AND OTHER TRADING RESTRICTIONS UNDER FEDERAL SECURITIES LAWS

A. Section 16(a) Reporting Requirements

Section 16(a) of the Exchange Act requires that Cartesian's insiders file electronic beneficial ownership reports in connection with their purchases and sales of the Company's securities. Securities and Exchange Commission ("SEC") rules require that all filings be made with the SEC electronically and on Cartesian's website. Further, Cartesian is required to disclose in its annual proxy statement the names of all insiders who have failed to timely file all required Section 16(a) reports.

1. Form 3

An insider must file a Form 3 (entitled "Initial Statement of Beneficial Ownership of Securities") with the SEC to report that he or she is an insider and his or her ownership interests

in Cartesian. Anyone becoming an insider in the future must file a Form 3 within ten days of becoming an insider.

2. Forms 4 and 5

An insider must file a Form 4 (entitled "Statement of Changes in Beneficial Ownership") with the SEC to report a transaction within two business days after the date of such transaction if it results in a change in his or her beneficial ownership of Cartesian's equity securities. There are three general exceptions to the two-business-day reporting requirement.

First, the following types of transactions may be reported on a Form 4 within two business days following the date the insider receives *notice of the transaction* (but in no event later than five business days following the transaction), rather than two business days following the date on which the transaction occurs:

- a transaction pursuant to a Rule 10b5-1 plan under which the insider does not select the date on which the purchases or sales take place; and
- a "discretionary transaction" (as defined in Rule 16b-3) pursuant to an employee benefit plan for which the insider does not select the date on which transactions take place (such as transfers in or out of, or cash withdrawals from, a company stock fund in a 401(k) plan or other employee benefit plan).

Second, certain transactions may, and in a few instances must, be reported on a year-end Form 5 (entitled "Annual Statement of Changes in Beneficial Ownership of Securities"). A Form 5 must be filed with the SEC within 45 days after the end of such fiscal year by each person who was an insider for any part of a company's fiscal year (unless he or she has no transactions to report on the Form 5). There are certain limited types of stock transactions that the SEC has designated as eligible for Form 5 filing (rather than a Form 4 filing). Insiders also must report on a Form 5 all transactions that occurred during the fiscal year that should have been, but were not, reported earlier on Form 4.

Third, the following types of transactions do not trigger any Form 4 or Form 5 filing requirement:

- an acquisition under an employee stock purchase plan;
- a transaction (other than a "discretionary transaction") under certain employee benefit plans, such as pension plans, 401(k) plans, or related excess benefit plans;
- an acquisition through a stock split, stock dividend or other pro rata distribution to stockholders of the Company;
- an acquisition under certain dividend or interest reinvestment plans; and
- an acquisition or disposition as a result of a domestic relations orders (such as a divorce decree).

Although these transactions do not require the filing of a Form 4 or Form 5, the next Form 4 or Form 5 filed after the occurrence of one of these transactions should reflect the effects of these transactions in the column reporting post-transaction security ownership.

3. Preparation of Forms 3, 4 and 5

Although the responsibility for the timely filing of reports and compliance with trading restrictions rests with each individual required to report or comply, the General Counsel will prepare and file Forms 3, 4, and 5 on behalf of insiders who are Company directors and officers. All Forms 3, 4, and 5 prepared on behalf of an insider will be based on information provided by the insider. Accordingly, all insiders must fill out and deliver to the General Counsel a Form ID (a form to obtain access codes to file on the SEC's electronic filing system).

B. Section 16(b) Short-Swing Profit Liability

Section 16(b) of the Exchange Act allows the Company to recover any profit realized by one of its insiders resulting from any combination of purchases and sales of Cartesian's equity securities within a period of less than six months. Such liability arises without regard to whether any such transactions occur during the Window Period referred to above. Profits are determined for this purpose by matching the highest sales price during the period with the lowest purchase price and are to be recovered even though the insider realized no actual profit for the period or he or she sustained a net loss. Although the purpose of the statute is to prevent trading on the basis of material nonpublic information, the recovery provision operates without regard to the intent of the insider or the actual possession of material nonpublic information and may not be waived by the Company.

The restrictions on "short-swing" trading apply not only to trading in Cartesian's securities but also to any "derivative security." Thus, for example, a grant or exercise of options (other than grants or exercises made under a plan that is exempt from Section 16) would be considered to be a "purchase" or sales of Cartesian securities under Section 16. Other transactions not necessarily thought to involve purchases, such as corporate mergers, also may be covered. The SEC has exempted certain transactions, such as purchases under employee benefit plans that have been approved by stockholders or the board of directors, from the "short-swing" profit recovery provisions of Section 16 (but not the reporting provisions). Directors and officers remain subject to these Section 16 requirements and restrictions for a period of up to six months after terminating their positions with Cartesian.

Exhibit 21.1

Subsidiaries of Cartesian Therapeutics, Inc.:

Name	Jurisdiction of Organization
Selecta (RUS) LLC	Russia
Cartesian Bio, LLC	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8, File No. 333-212215) pertaining to the 2008 Stock Incentive Plan, as amended, the 2016 Incentive Award Plan and the 2016 Employee Stock Purchase Plan of Cartesian Therapeutics, Inc.,

(2) Registration Statement (Form S-8, File No. 333-224109) pertaining to the 2016 Incentive Awards Plan and the 2016 Employee Stock Purchase Plan of Cartesian Therapeutics, Inc.,

(3) Registration Statement (Form S-8, File No. 333-228264) pertaining to the 2018 Employment Inducement Incentive Award Plan of Cartesian Therapeutics, Inc.,

(4) Registration Statement (Form S-8, File No. 333-230501) pertaining to the 2018 Employment Inducement Incentive Award Plan of Cartesian Therapeutics, Inc.,

(5) Registration Statement (Form S-8, File No. 333-239075) pertaining to the 2016 Incentive Award Plan and the 2016 Employee Stock Purchase Plan of Cartesian Therapeutics, Inc.,

(6) Registration Statement (Form S-8, File No. 333-256061) pertaining to the 2016 Incentive Award Plan and the 2016 Employee Stock Purchase Plan of Cartesian Therapeutics, Inc.,

(7) Registration Statement (Form S-8, File No. 333-264691) pertaining to the 2016 Incentive Award Plan and the 2016 Employee Stock Purchase Plan of Cartesian Therapeutics, Inc.,

(8) Registration Statement (Form S-8, File No. 333-274036) pertaining to the 2016 Incentive Award Plan and the 2016 Employee Stock Purchase Plan of Cartesian Therapeutics, Inc.,

(9) Registration Statement (Form S-3, File No. 333-275171) of Cartesian Therapeutics, Inc.,

(10) Registration Statement (Form S-8, File No. 333-276486) pertaining to the 2016 Stock Incentive Plan and the 2018 Employment Inducement Incentive Award Plan of Cartesian Therapeutics, Inc.,

(11) Registration Statement (Form S-1, File No. 333-281204) of Cartesian Therapeutics, Inc.,

(12) Registration Statement (Form S-8, File No. 333-283049) pertaining to the Amended and Restated 2016 Incentive Award Plan and the Amended and Restated 2018 Employment Inducement Incentive Award Plan of Cartesian Therapeutics, Inc.,

(13) Registration Statement (Form S-3, File No. 333-283803) of Cartesian Therapeutics, Inc.,

(14) Registration Statement (Form S-3, File No. 333-283806) of Cartesian Therapeutics, Inc.,

(15) Registration Statement (Form S-3, File No. 333-283809) of Cartesian Therapeutics, Inc., and

(16) Registration Statement (Form S-8, File No. 333-287062) pertaining to the Amended and Restated 2016 Incentive Award Plan and the Amended and Restated 2018 Employment Inducement Incentive Award Plan of Cartesian Therapeutics, Inc.;

of our report dated March 9, 2026 with respect to the consolidated financial statements of Cartesian Therapeutics, Inc. included in this Annual Report (Form 10-K) of Cartesian Therapeutics, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 9, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Carsten Brunn, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Cartesian Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 9, 2026

/s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Blaine Davis, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cartesian Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 9, 2026

/s/ Blaine Davis
Blaine Davis
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cartesian Therapeutics, Inc. (the "Company") for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

1. The Annual Report on Form 10-K of the Company for the period ended December 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 9, 2026

/s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President, Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)

March 9, 2026

/s/ Blaine Davis
Blaine Davis
Chief Financial Officer
(Principal Financial Officer)