UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 3, 2025

CARTESIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-37798**	**26-1622110**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS 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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (Par Value $0.0001)	RNAC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 7.01. Regulation FD Disclosure.

Cartesian Therapeutics, Inc. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. A copy of its current corporate slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information in Item 7.01 of this Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Corporate slide presentation of Cartesian Therapeutics, Inc. dated March 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CARTESIAN THERAPEUTICS, INC.

Date: March 3, 2025

By: /s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President and Chief Executive Officer

Exhibit 99.1


Cartesian
therapeutics
Pioneering mRNA Cell Therapy for Autoimmunity
March 2025

Forward-looking statements

Disclosures

For the purposes of this notice, the “presentation” that follows shall mean and include the slides that follow, the oral presentation of the slides by members of management of Cartesian Therapeutics, Inc. (the “Company”) or any person on their behalf, any question-and-answer session that follows such oral presentation, hard copies of this document and any materials distributed at, or in connection with, such oral presentation.

The Company’s product candidates are investigational clinical products currently under clinical evaluation and study the Company’s product candidates have not been approved for use by the U.S. Food and Drug Administration ("FDA"). Any reference to the Company’s product candidates’ potential benefits, safety, or efficacy is based on observations from ongoing clinical research and should not be interpreted as definitive clinical evidence. Use or discussion of the Company’s product candidates is limited to the context of clinical research and free scientific exchange of information and is not intended for the general public, as medical advice, nor as any suggestion or indication that the Company’s product candidates have been found by the FDA to be safe or effective or approved for use outside of clinical trials.

Forward-looking Statements

Any statements in this presentation about the future expectations, plans and prospects of the Company, including without limitation, statements about the Company’s expected cash resources and cash runway, statements regarding the ability of the Company’s product candidates to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the potential of Descartes-08, Descartes-15, or any of the Company’s other product candidates to treat myasthenia gravis, juvenile myasthenia gravis, systemic lupus erythematosus, juvenile systemic lupus erythematosus, juvenile dermatomyositis, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, the anticipated timing or the outcome of the FDA’s review of the Company’s regulatory filings, the Company’s ability to conduct its clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the novelty of treatment paradigms that the Company is able to develop, the potential of any therapies developed by the Company to fulfill unmet medical needs, and enrollment in the Company’s clinical trials and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “hypothesize,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including uncertain outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company’s technology, potential delays in enrollment of patients, undesirable side effects of the Company’s product candidates, political uncertainty, the Company’s reliance on third parties to conduct its clinical trials, the Company’s inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company’s recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company’s common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the “Risk Factors” section of the Company’s most recent Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this presentation represent the Company’s views only as of the date of its publication and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any intention to update any forward-looking statements included in this presentation, except as required by law.

Clinical-stage company pioneering mRNA cell therapies designed to expand the reach of cell therapy to autoimmunity

- Pipeline of mRNA cell therapies designed to be dosed more reliably and safely in an outpatient setting ***without lymphodepletion***
- Descartes-08: Investigational mRNA CAR T-cell (CAR-T) with ***deep and durable responses*** observed in randomized, double-blind, placebo-controlled Phase 2b trial in patients with myasthenia gravis (MG)
- ***Wholly-owned GMP manufacturing*** designed to enable rapid optimization of processes in iterative manner

MULTIPLE ANTICIPATED NEAR-TERM CATALYSTS

DESCARTES-08

- Phase 3 AURORA study expected to commence in 1H25
- Open-label Phase 2 trial ongoing in Systemic Lupus Erythematosus (SLE); data readout expected in 2H25
- Pediatric basket trial expected to initiate in 2H25

DESCARTES-15

- Next-generation mRNA CAR-T candidate
- Dosing underway in first-in-human Phase 1 dose escalation trial

CASH RESOURCES

- ***Strong balance sheet with approximately $220.9 million****
- Expected to support planned operations, including completion of planned Phase 3 trial of Descartes-08 for MG, into mid-2027

* As of September 30, 2024.
GMP, Good manufacturing practices
CAR, Chimeric antigen receptor
IND, Investigational new drug application

Cartesian therapeutics

Cartesian's mRNA approach is designed to expand the reach of potent cell therapy products to address autoimmunity

No Lymphodepletion

No associated cytopenia, secondary malignancies, or other chemotherapy toxicities

Administered Outpatient

Convenient dosing schedule

Delivered at Therapeutic Levels

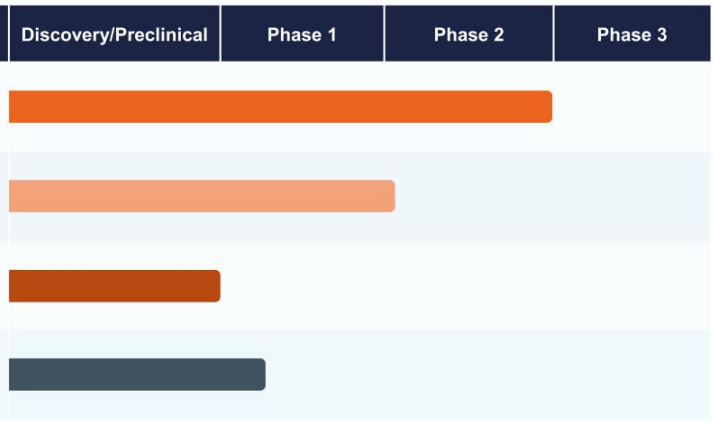
Administered at therapeutic doses without uncontrollable proliferation

Transient Cell Modification

Does not carry risk of genomic integration

Wholly-owned pipeline targets autoimmune disease

Asset	Indications	Discovery/Preclinical	Phase 1	Phase 2	Phase 3
Descartes-08 Autologous mRNA CAR-T	Myasthenia Gravis (MG)				
	Systemic Lupus Erythematosus (SLE)				
	Pediatric Autoimmune Diseases*				
Descartes-15 Autologous mRNA CAR-T	Autoimmune Diseases**				



* IND filing made for Phase 2 pediatric basket trial, includes juvenile SLE, juvenile MG and other conditions.
** Dosing in Phase 1 dose escalation trial in myeloma underway.

Myasthenia gravis is a rare, progressive autoimmune disease with significant unmet need

>120,000
Patients in the U.S. and EU

Significant unmet need remains

Characterized by debilitating fatigue and muscle weakness

Current treatments require chronic or frequent administration and have limited durability

Cartesian Therapeutics

Deep and durable responses maintained over 12 months in participants treated with Descartes-08 in Phase 2b

Deepening responses observed over time

Durable responses observed over time

Deepest responses observed in participants without exposure to prior biologic therapy

Safety profile continues to support outpatient administration

Planned Phase 3 AURORA study design finalized following meeting with U.S. FDA

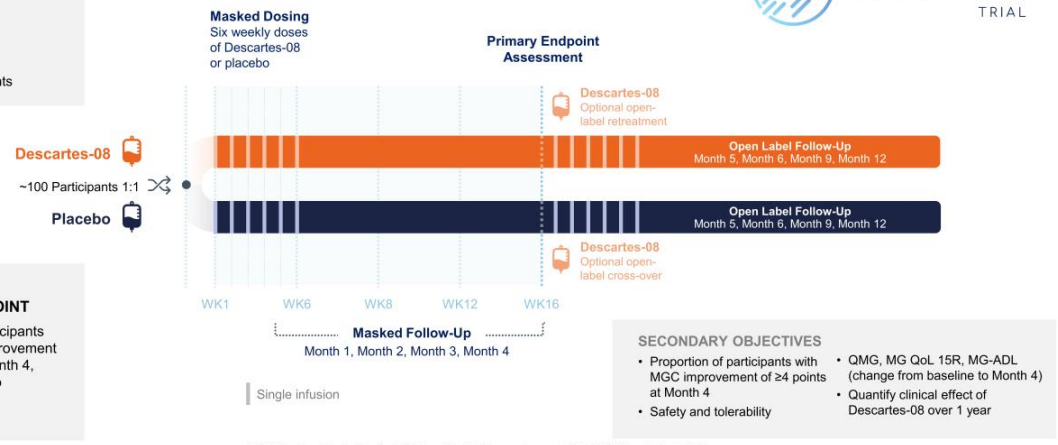
- Primary endpoint to assess MG-ADL improvement of ≥3 points at Month 4 relative to placebo
- Expected to commence in 1H25

AURORA: Randomized double-blind, placebo-controlled Phase 3 trial of Descartes-08 in AChR Ab+ gMG expected to commence in 1H 2025

aurora TRIAL

INCLUSION CRITERIA

- AChR Ab+
- MGFA Class II-IV
- MG-ADL ≥6
- On stable doses of immunosuppressants



PRIMARY ENDPOINT

- Proportion of participants with MG-ADL improvement of ≥3 points at Month 4, relative to placebo

SECONDARY OBJECTIVES

- Proportion of participants with MGC improvement of ≥4 points at Month 4
- Safety and tolerability
- QMG, MG QoL 15R, MG-ADL (change from baseline to Month 4)
- Quantify clinical effect of Descartes-08 over 1 year

MG-ADL, Myasthenia Gravis Activities of Daily Living scale
gMG, Generalized myasthenia gravis
MGFA, Myasthenia Gravis Foundation of America
MGC, Myasthenia Gravis Composite

MG QMG, Quantitative MG Scores
MG QoL 15R, MG Quality of Life 15-revised
AChR Ab+, Acetylcholine receptor autoantibody positive

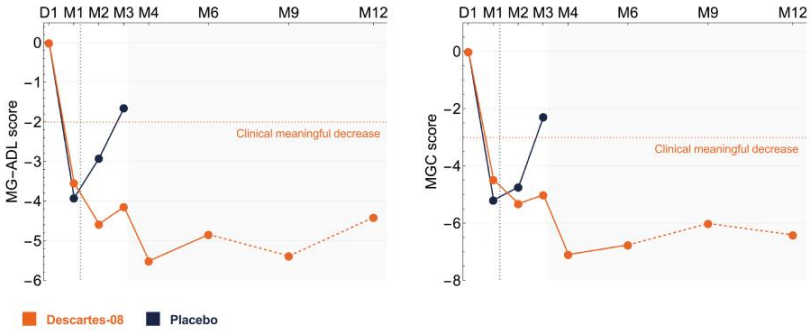
Cartesian therapeutics

Descartes-08 in Myasthenia Gravis Phase 2b Results

Cartesian therapeutics

Deepening responses observed in participants treated with Descartes-08

Primary Efficacy Dataset



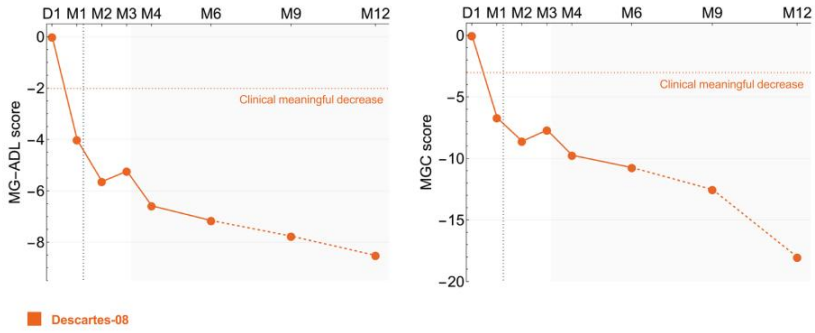
Month 3 (n=14), Month 4 (n=12*), Month 6 (n=12), Month 9 (n=8), Month 12 (n=5)
**Two participants lost to follow-up*

- Average MG-ADL reduction of 5.5 (±1.1) points at Month 4
- 33% of participants achieved minimum symptom expression at Month 6
- 80% of participants reaching Month 12 maintained clinically meaningful response

Minimum symptom expression: MG-ADL 0-1

Deepest responses observed in participants with no prior exposure to complement or FcRn inhibitors

Primary Efficacy Dataset (No Prior Biologics)



Descartes-08

Month 3 (n=9), Month 4 (n=7*), Month 6 (n=7), Month 9 (n=4), Month 12 (n=2)
**Two participants lost to follow-up*

- Average MG-ADL reduction of 6.6 (±1.5) points at Month 4
- 57% of participants achieved minimum symptom expression at Month 6
- 100% of participants reaching Month 12 maintained clinically meaningful response

Cartesian Therapeutics

Safety profile supports outpatient administration

	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%)					

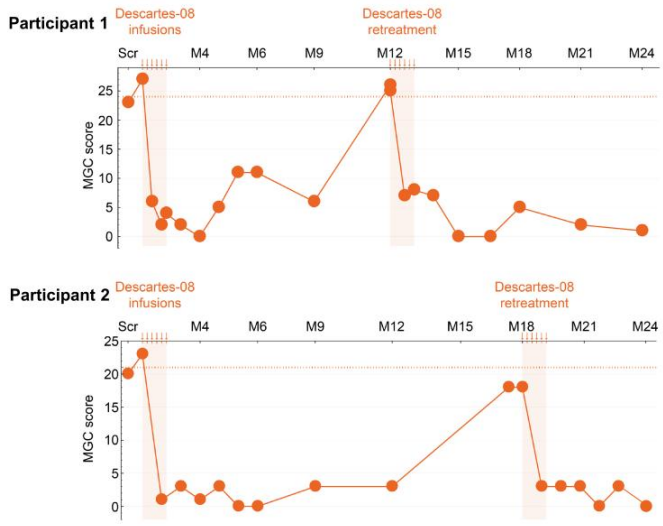
- **No new type of AEs reported**
- **No hypogammaglobulinemia or increased infections reported**
- **No difference in vaccine titers between Descartes-08 and placebo**

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

AE, Adverse event

Phase 2a trial update: Descartes-08 retreatment continues to elicit deep and durable responses



- Three participants retreated to date, two of whom maintain minimum symptom expression 2 years after initial treatment
- Third participant achieved 4-point reduction in MG-ADL and 6-point reduction in MGC at the most recent, Month 2 follow-up of retreatment

Manuscript submitted for peer review; pre-print available at medRxiv.org.

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Additional Indications and Pipeline

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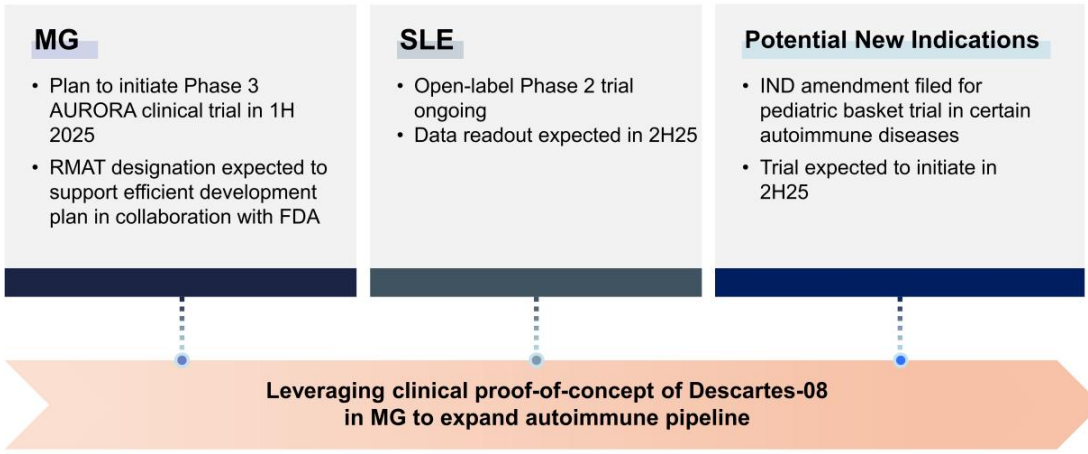
Intend to leverage the potential of Descartes-08 across multiple clinical programs



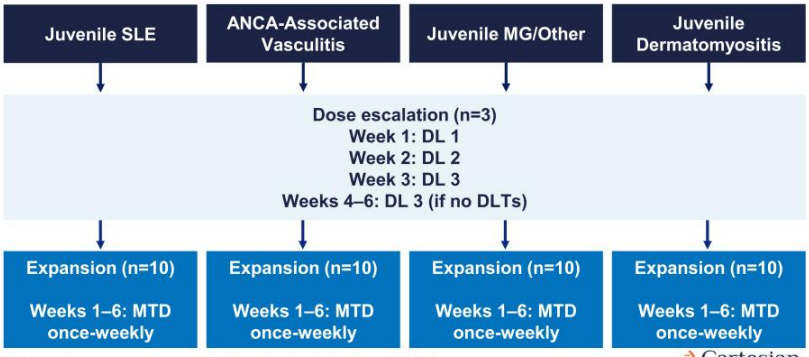
Descartes-08 has the potential to address pediatric indications, a severely underserved population

DC-08's observed safety profile combined with significant unmet need in pediatric autoimmune disease supports clinical development plan

- No lymphodepleting chemotherapy
- No integrating vectors
- Fully outpatient treatment with 1hr post-infusion monitoring
- No observed CRS or ICANS

Anticipated Pediatric Basket Trial Timeline

- Rare Pediatric Disease Designation for DC-08 in juvenile dermatomyositis granted in September 2024
- IND amendment filed to include DC-08 in juvenile SLE in December 2024
- Pediatric basket trial expected to initiate in 2H25



DL – Dose level
DLT – Dose limiting toxicity

ANCA – Anti-Neutrophil Cytoplasmic Antibody
MTD – Maximum tolerated dose

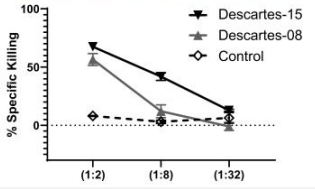
Cartesian therapeutics

Descartes-15, a next generation anti-BCMA mRNA CAR-T with >10x potency observed in preclinical studies

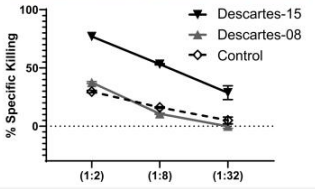
Descartes-15 is an anti-BCMA mRNA CAR-T with potential disruptive features:

- Engineered for maximum potency and CAR stability, even in the presence of target-driven suppression of CAR
- Clinical strategy expected to leverage safety and clinical activity data from Descartes-08
- Phase 1 trial ongoing

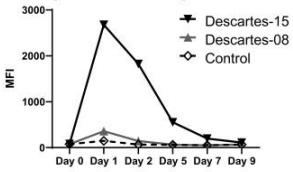
Potent killing (single target exposure)



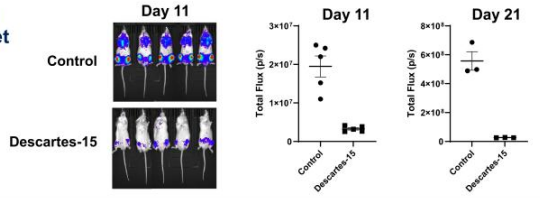
Persistent killing (multiple exposures)



Superior CAR expression



Efficient killing of BCMA+ target cells*



*MM1-S disseminated myeloma model in NSG mice infused with either control T-cells or Descartes-15.

Cartesian therapeutics

STRONG FINANCIAL POSITION:

Expected to Support Pipeline Through Key Milestones

$220.9M

In cash, cash equivalents and restricted cash as of 9/30/24

<70 FULL TIME EMPLOYEES

Based in Frederick, MD and Gaithersburg, MD

25.8M

Basic shares outstanding as of 12/31/24

33.1M

Fully diluted shares outstanding*

* As of 12/31/24. Further includes Series A Non-Voting Convertible Preferred Stock and Series B Non-Voting Convertible Preferred Stock that remain subject to beneficial ownership limitations that are convertible into shares of common stock and includes outstanding options, RSUs and warrants.


Cartesian®
therapeutics