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): January 13, 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.

Additionally, on January 13, 2025, the Company issued a press release announcing its 2025 strategic priorities. This press release is attached to this Current Report on Form 8-K as Exhibit 99.2.

The information in Item 7.01 of this Form 8-K, including Exhibits 99.1 and 99.2 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 Exhibits 99.1 or 99.2, 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 January 2025.
99.2	Press release of Cartesian Therapeutics, Inc. issued on January 13, 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: January 13, 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
January 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.

Descartes-08 is an investigational clinical product candidate currently under clinical evaluation and study. Descartes-08 has not been approved for use by the U.S. Food and Drug Administration ("FDA"). Any reference to Descartes-08's 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 Descartes-08 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 Descartes-08 has 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 observations and data from the myasthenia gravis Phase 2a/2b trial, 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, 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 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, its 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
- IND filing made for Phase 2 pediatric basket trial

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

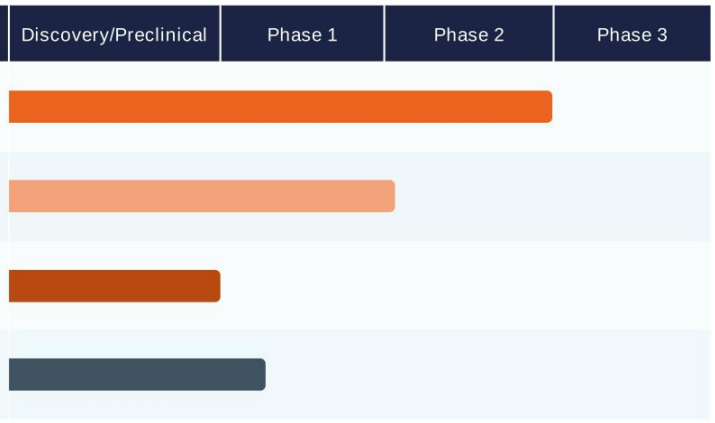
Administered at therapeutic doses without uncontrollable proliferation

Transient Cell Modification

Does not carry risk of genomic integration

Wholly-owned pipeline targets autoimmune disease

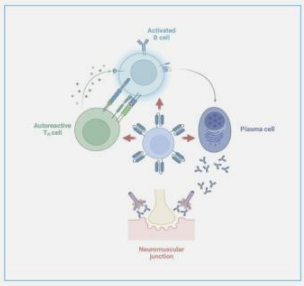
Asset	Indications	Discovery/Preclinical	Phase 1	Phase 2	Phase 3
Descartes-08 Autologous mRNA CAR-T	Myasthenia Gravis (MG)				
	Systemic Lupus Erythematosus (SLE)				
	Pediatric Autoimmune Diseases*				
Descartes-15 Autologous mRNA CAR-T	Autoimmune Diseases**				



* 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.

Descartes-08 is an mRNA CAR T-cell therapy in clinical development for autoimmune disease

- Engineered by transfection of autologous CD8+ T cells with mRNA encoding anti-BCMA CAR
- Typical lot processed for infusion within as little as ~3 weeks
- Granted U.S. FDA orphan and RMAT designations for generalized myasthenia gravis, and RPDD for juvenile dermatomyositis



RMAT, Regenerative Medicine Advanced Therapy
RPDD, Rare Pediatric Disease Designation
FDA, U.S. Food and Drug Administration
BCMA, B-cell maturation antigen

Descartes-08 in Myasthenia Gravis

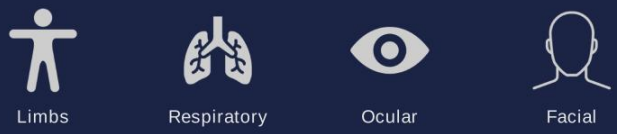
Cartesian Therapeutics

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

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

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

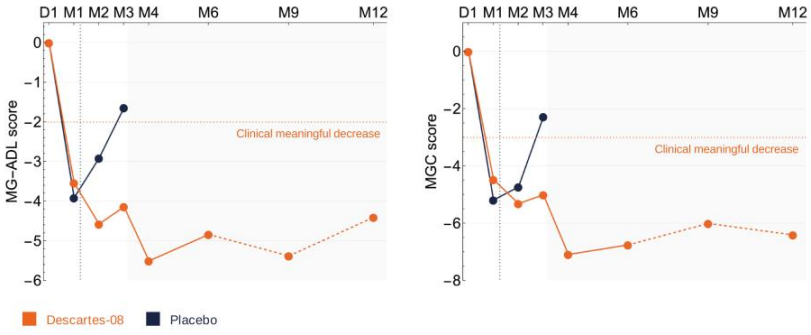
Safety profile continues to support outpatient administration

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

Deepening responses observed in participants treated with Descartes-08

Primary Efficacy Dataset



Descartes-08 Placebo

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

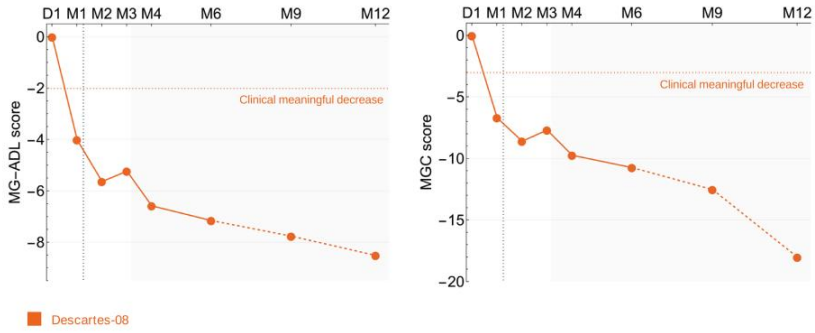
- Average MG-ADL reduction of 5.5 (±1.1) points at Month 4
- 33% of participants achieved minimum symptom expression at Month 6
- 80% of participants reaching Month 12 maintained clinically meaningful response

Minimum symptom expression: MG-ADL 0-1

Cartesian therapeutics

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%)					

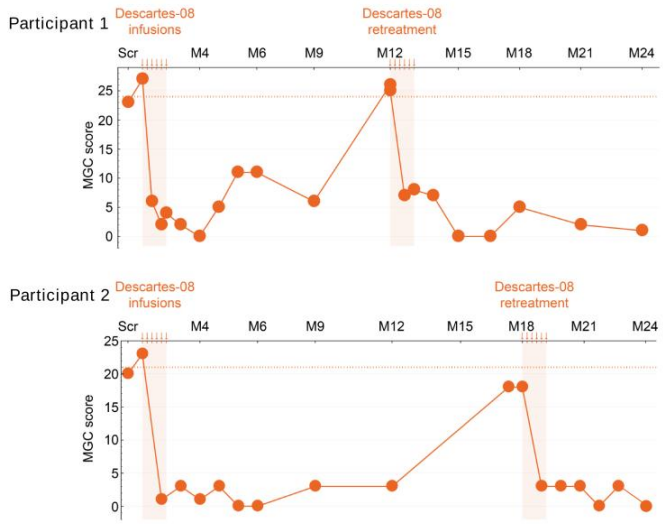
- No new type of AEs reported
- No hypogammaglobulinemia or increased infections reported
- No difference in vaccine titers between Descartes-08 and placebo

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



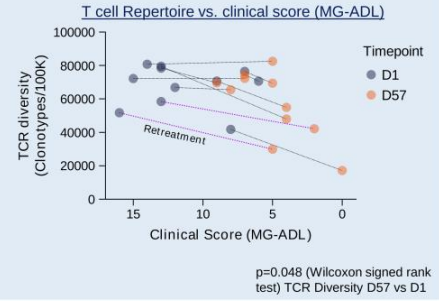
- Three participants retreated to date, two of whom maintain minimum symptom expression 2 years after initial treatment
- Third participant achieved 4-point reduction in MG-ADL and 6-point reduction in MGC at the most recent, Month 2 follow-up of retreatment

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

Cartesian therapeutics

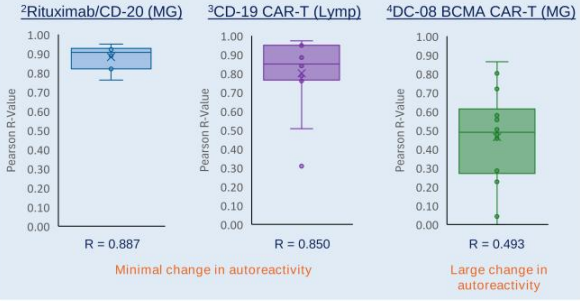
Descartes-08 focuses the T-cell repertoire and selectively alters the autoreactome, showing clear biological activity

Descartes-08 focuses the T-cell repertoire in a manner that correlates with clinical effect



Data show Clinical Score and TCR Sequencing TCR Diversity (Downsampled Rearrangements) in Phase 2a samples analyzed at Adaptive Biotechnologies (R06 dataset). For certain subjects where TCR sequencing sample data was unavailable, D1 data was imputed from Screen, and D57 data was imputed from D85. Samples from one re-treated patient were analyzed as indicated. P-value is provided for Wilcoxon matched-pairs signed rank test on all primary-treatment data pairs from D1 vs D57.

Descartes-08 selectively alters the self-reactive branch of the antibody repertoire (i.e., autoreactome[1])



[1]Bodansky et al., Journal of Clinical Investigation 2024, doi: 10.1101/2023.12.19.23300188.

Serum analysis of [2]Myasthenia gravis patients receiving Rituximab targeting CD20+ B cells, [3]lymphoma patients receiving conventional CD19 DNA CAR-T, or [4]gMG patients following infusion with DC-08. Data compare D85 to D1 for MG open label cohort (N=13).

Cartesian therapeutics

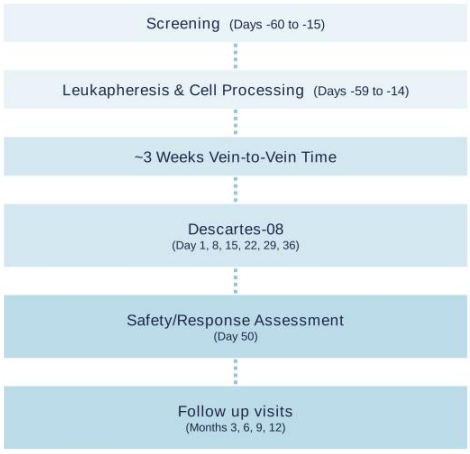
Descartes-08
Additional Indications

Cartesian Therapeutics

Exploring potential of Descartes-08 in Systemic Lupus Erythematosus (SLE)

PHASE 2 TRIAL ONGOING

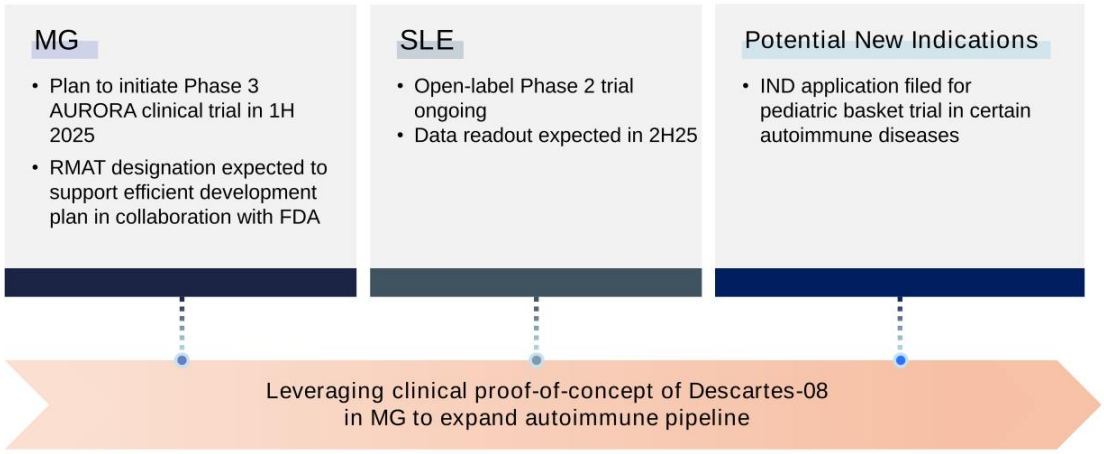
- Open-label trial in up to 30 adults with moderate to severe multi-refractory SLE and no CNS involvement
- Designed to assess safety, tolerability, and manufacturing feasibility of Descartes-08 in patients with SLE
- Secondary objectives include standard measures of clinical activity in SLE:
  - Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K)
  - Physician Global Assessment (PGA)
  - Systemic Lupus Erythematosus Responder Index (SRI)
  - British Isles Lupus Assessment Group (BILAG)–based Composite Lupus Assessment (BICLA)
- Data readout expected in 2H25



CNS, Central nervous system

Cartesian Therapeutics

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



Descartes-15

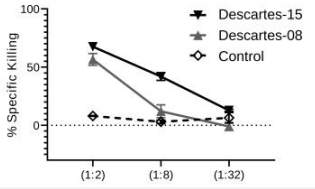
Cartesian Therapeutics

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

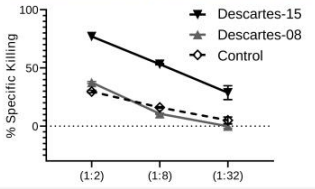
Descartes-15 is an anti-BCMA mRNA CAR-T with potential disruptive features:

- 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

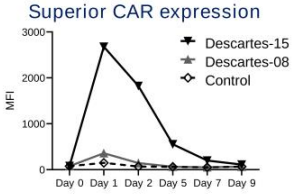
Potent killing (single target exposure)



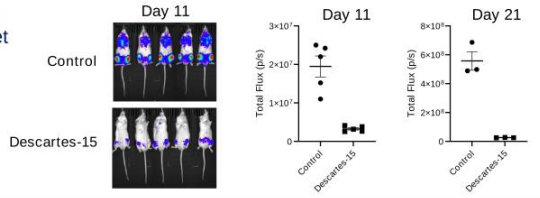
Persistent killing (multiple exposures)



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

Wholly-owned, in-house manufacturing

~30,000 sq. ft. state-of-the-art cGMP facility

Facility located in Frederick, MD

FUTURE GROWTH

Clinical and commercial manufacturing scale capabilities support maturing pipeline and future growth

QUICK TO ADAPT

Flexibility to quickly adapt to changes in processes or needs

WHOLLY-OWNED

Ownership of quality control and production timelines

COST EFFICIENT

Potential cost efficiency

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 Gaithersburg, MD and Frederick, 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.

Our team | Management

Carsten Brunn, PhD
PRESIDENT AND CEO

Blaine Davis
CHIEF FINANCIAL OFFICER

Metin Kurtoğlu, MD, PhD
CHIEF TECHNOLOGY OFFICER

Miloš Miljković, MD
CHIEF MEDICAL OFFICER

Chris Jewell, PhD
CHIEF SCIENTIFIC OFFICER

Jessica Keliher
CHIEF PEOPLE OFFICER

Emily English, PhD
CHIEF OPERATIONS OFFICER

Matthew Bartholomae
GENERAL COUNSEL, SECRETARY

Key Takeaways

Pioneering mRNA Cell Therapies

Pipeline designed to expand the reach of cell therapy to autoimmunity

Experienced Leadership Team

Focused on disciplined investment and creating value for stockholders and patients

Strong Balance Sheet to Support Maturing Pipeline

Current cash expected to support Descartes-08 through the completion of Phase 3 in mid-2027

Maturing Pipeline with Expected Near-term Catalysts

- Descartes-08 in MG: Phase 3 AURORA trial initiation planned for 1H25
- Descartes-08 in SLE: Enrollment in Phase 2 open-label trial ongoing; data readout expected in 2H25
- Descartes-08 Pediatric Basket Trial: IND filing made for Phase 2 study
- Descartes-15: Phase 1 first-in-human trial ongoing


Cartesian®
therapeutics

Appendix

Phase 2b trial: double-blind, placebo-controlled clinical trial of Descartes-08 in patients with myasthenia gravis

INCLUSION CRITERIA

- Non-MuSK-MG
- MGFA Class II-IV
- MG-ADL ≥6
- Severe disease despite stable doses of immunosuppressants

PRIMARY ENDPOINT

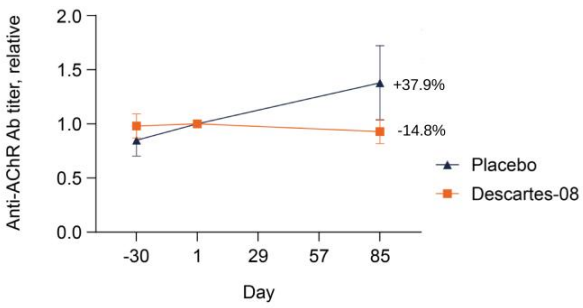
- Proportion of patients with MG Composite improvement of ≥5-points at Month 3, relative to placebo
- Predefined primary efficacy dataset

SECONDARY OBJECTIVES

- Safety and tolerability from predefined safety dataset
- Quantify clinical effect of Descartes-08 over 1 year
- QMG, MG QoL 15R, MG-ADL (change from baseline to Month 3)
- Compare effect of Descartes-08 versus placebo on MG scales (change from baseline to Month 3) in patients who cross over from placebo to Descartes-08

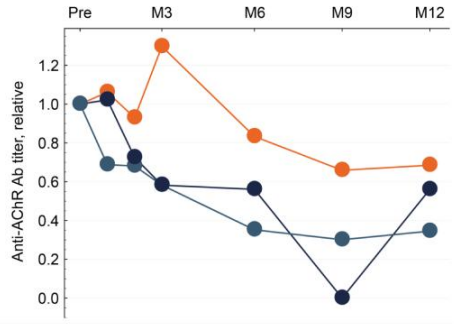
Cartesian therapeutics

Approximately 15% reduction in AChR antibody titer at Month 3 is in line with Phase 2a data



Average reduction (±SEM) in AChR antibody in participants with baseline levels above LLOQ randomized to Descartes-08 (n=12) vs. Placebo (n=9).

Phase 2a data

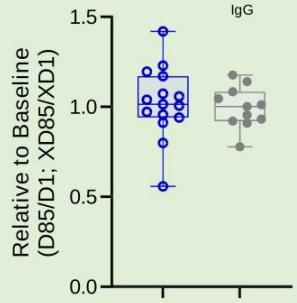


Individual Anti-AChR antibody titers in all participants receiving six once-weekly infusions in the Phase 2a trial with detectable baseline levels (n=3).

SEM, Standard error of the mean
LLOQ, Lower limit of quantification

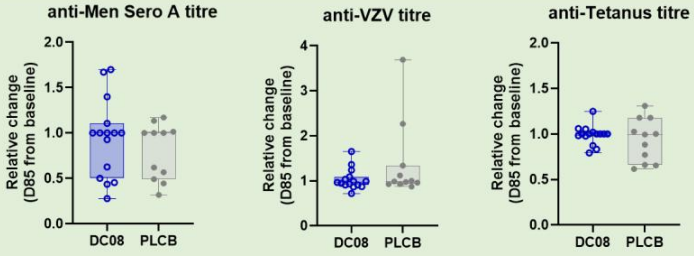
Descartes-08 observed not to deplete broader antibody repertoire or decrease vaccine titers for common viruses

No significance change in Ig at primary end point (D85) vs. Day 1[1]



Descartes-08 (DC08) Placebo (PLCB)

No significant change in common vaccine titers at primary end point (Day 85) relative to Day 1[2]



Not shown: anti-Men Sero C, anti-Men Sero W135, anti-Men Sero Y, anti-Diphtheria, anti-Measels, anti-Mumps and anti-Rubella titers

Descartes-08 (DC08) Placebo (PLCB)

1. Data indicate change in Ig levels for each participant in the mITT group (n = 26) at Day 85 relative to Day 1. Data are individual values, median, range and IQR.
2. Data indicate change in vaccines titers for each participant in the mITT group (n=26) at Day 85 relative to Day 1. Data are individual values, median, range and IQR.

Ig, Immunoglobulin
VZV, Varicella zoster virus
mITT, Modified intent-to-treat

Cartesian therapeutics

Descartes-08 is designed for dual action, precisely targeting two key BCMA+ cell populations involved in a spectrum of autoimmune diseases

Descartes-08 is designed to target BCMA, a surface antigen expressed on plasma cells/plasmablasts and plasmacytoid dendritic cells

PLASMA CELLS (PCs) AND PLASMABLASTS

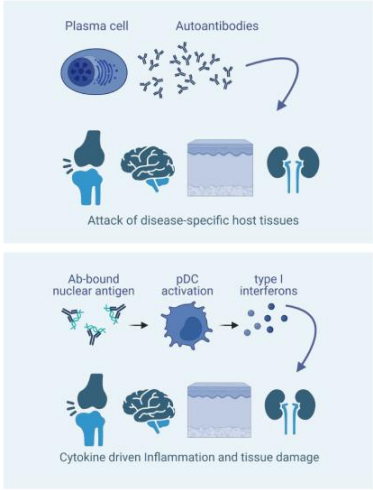
- PCs, plasmablasts and proliferating B cells targeted by Descartes-08 represent a tiny fraction of B cells
- These cells are entirely responsible for secreting pathogenic autoantibodies
- During autoimmunity, autoantibodies attack host tissue and drive inflammation

PLASMACYTOID DENDRITIC CELLS (pDCs)

- pDCs, which Descartes-08 is designed to target, are a rare subset of antigen-presenting cells
- These cells secrete high levels of cytokines (i.e., type I interferons) that cause inflammation and tissue damage during many human autoimmune diseases
- pDCs are increased in patients with autoimmunity (e.g., SLE) and interfere with optimal treatment

Several autoimmune disease segments involve pathogenic contributions from both PCs/plasmablasts and pDCs, including rheumatology, nephrology, neurology, and others

Selectively deleting PCs/plasmablasts and pDCs, if successful, may create a differentiated cell therapy platform



Cartesian Therapeutics Highlights Progress and 2025 Strategic Priorities Across Pipeline of mRNA Cell Therapies for Autoimmune Diseases

Phase 3 AURORA trial of Descartes-08 in myasthenia gravis on track to commence in 1H25

Deepening responses observed over time in Descartes-08-treated participants in Phase 2b trial in myasthenia gravis; Safety profile continues to support outpatient administration based on updated data shared in December 2024

Phase 2 systemic lupus erythematosus (SLE) trial of Descartes-08 ongoing with expected data readout in 2H25

Cash resources expected to support planned operations, including completion of planned Phase 3 trial for Descartes-08 for myasthenia gravis, into mid-2027

FREDERICK, Md., Jan. 13, 2025 (GLOBE NEWSWIRE) – Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering mRNA cell therapy for autoimmune diseases, today highlighted its recent progress and outlined its 2025 strategic priorities across its pipeline of mRNA cell therapy product candidates.

"On the heels of what was a highly productive 2024, we are entering the new year with strong momentum and believe we are well positioned to continue to make meaningful progress advancing our pipeline in 2025," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "With respect to Descartes-08 for the treatment of myasthenia gravis (MG), we recently shared updated Phase 2b results which continue to support the potential for Descartes-08 to provide deep and durable improvements for patients with MG in the convenient outpatient setting without the need for preconditioning chemotherapy. We believe these results provide strong support for the design of our planned Phase 3 program in this patient population, and we remain on track to commence our Phase 3 AURORA trial in the first half of this year."

Dr. Brunn continued, "In addition, we remain focused on exploring the potential of Descartes-08 beyond MG, with enrollment ongoing in our Phase 2 open-label trial in patients with systemic lupus erythematosus (SLE), and our planned Phase 2 basket trial in pediatric patients with select autoimmune conditions expected to commence later this year. We also continue to develop our work of Descartes-15, our next-gen, autologous anti-BCMA mRNA CAR-T cell therapy, as we move through our Phase 1 dose escalation trial."

Program Updates and Anticipated 2025 Milestones

Descartes-08

- In December 2024, the Company announced positive updated results from the Phase 2b trial of Descartes-08 in participants with MG. Deepening responses were observed over time, with Descartes-08-treated participants included in the primary efficacy dataset (n=12) experiencing an average MG Activities of Daily Living (MG-ADL) reduction of 5.5 (±1.1) at Month 4. Consistent

with previously reported data, Descartes-08 was observed to be well-tolerated, supporting outpatient administration without the need for lymphodepleting chemotherapy.

- The Company expects to commence its Phase 3 AURORA trial of Descartes-08 in patients with MG in the first half of 2025. The randomized, double-blind, placebo-controlled Phase 3 trial is designed to assess Descartes-08 versus placebo (1:1 randomization) administered as six once weekly infusions without preconditioning chemotherapy in approximately 100 participants with acetylcholine receptor autoantibody positive (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.

- Enrollment remains ongoing in the Company's Phase 2 open-label trial evaluating Descates-08 in SLE. The trial is designed to assess the safety, tolerability and clinical activity of outpatient Descartes-08 administration without preconditioning chemotherapy in patients with SLE. A data readout for this trial is expected in the second half of 2025. SLE is an incurable autoimmune disease marked by systemic inflammation that affects multiple organ systems and impacts approximately 1.5 million people in the United States.

- The Company expects to commence a Phase 2 basket trial of Descartes-08 in pediatric patients with select autoimmune diseases, including juvenile dermatomyositis (JDM), in 2025. The U.S. Food and Drug Administration (FDA) previously granted Rare Pediatric Disease Designation to Descartes-08 for the treatment of JDM, a rare pediatric autoimmune disorder.

Descartes-15

- Dosing is underway in the Company's first-in-human Phase 1 clinical trial of Descartes-15, its next-generation, autologous anti-BCMA mRNA CAR-T cell therapy. The Phase 1 dose escalation trial is designed to assess the safety and tolerability of outpatient Descartes-15 administration in patients with multiple myeloma. Following the Phase 1 dose escalation trial, the Company expects to subsequently assess Descartes-15 in autoimmune indications.

About Descartes-08

Descartes-08, Cartesian's lead mRNA cell therapy candidate, is an autologous mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA CAR-T) product targeting B-cell maturation antigen (BCMA) in clinical development for generalized myasthenia gravis (MG) and systemic lupus erythematosus. In contrast to conventional DNA-based CAR T-cell therapies, mRNA CAR-T administration is designed to not require preconditioning chemotherapy, can 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 for the treatment of MG, and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis.

About Descartes-15

Descartes-15 is a next-generation, autologous anti-BCMA mRNA CAR-T cell therapy. In preclinical studies, Descartes-15 has been observed to achieve an approximately ten-fold increase in CAR

expression and selective target-specific killing, relative to Descartes-08. Similar to Descartes-08, Descartes-15 is designed to be administered without preconditioning chemotherapy and does not use integrating vectors.

About Cartesian Therapeutics

Cartesian Therapeutics is a clinical-stage company pioneering mRNA cell therapy for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is an mRNA CAR-T in Phase 2b clinical development for patients with generalized myasthenia gravis and Phase 2 development for systemic lupus erythematosus, with a Phase 2 basket trial planned in additional autoimmune indications. The Company's clinical-stage pipeline also includes Descartes-15, a next-generation, autologous anti-BCMA mRNA CAR-T. For more information, please visit www.cartesiantherapeutics.com or follow the Company on LinkedIn or X, formerly known as Twitter.

Forward Looking Statements

Any statements in this press release 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 observations and data from the myasthenia gravis Phase 2a/2b trial, 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, 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 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, its 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 press release 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 press release, except as required by law.

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