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): December 3, 2024

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.

On December 3, 2024, Cartesian Therapeutics, Inc. (the "Company") issued a press release announcing positive updated results from its Phase 2b trial of Descartes-08 in patients with generalized myasthenia gravis ("MG") and outlining the design of its planned Phase 3 AURORA trial in patients with MG. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference. The Company will host a conference call to discuss the updated Phase 2b data and the planned Phase 3 AURORA trial on December 3, 2024 at 7:30 a.m., Eastern Time, and a live audio webcast of the call will be available through the Events & Presentations section of the Company's website. A copy of the slide presentation to be used during the presentation is attached hereto as Exhibit 99.2 and incorporated herein by reference.

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.

Item 8.01 Other Information.

On December 3, 2024, the Company announced positive updated efficacy and safety data from its Phase 2b trial of Descartes-08 in participants with MG. In the Phase 2b double-blind, placebo-controlled, crossover trial, a total of 36 heavily pre-treated, highly symptomatic participants with MG were randomized 1:1 to receive either Descartes-08 or placebo administered as six weekly outpatient infusions without preconditioning chemotherapy.

The primary efficacy dataset for the follow-up portion of the trial consisted of a modified intent-to-treat ("mITT") population of all subjects enrolled at academic medical centers who received at least one dose of Descartes-08 and completed at least one post-Month 3 MG Activities of Daily Living ("MG-ADL") score follow-up assessment. As of an October 31, 2024 cutoff date, 12 participants in the primary efficacy dataset completed their Month 4 and Month 6 follow-up assessments, with eight participants evaluable for their Month 9 assessment, and five participants evaluable for their Month 12 assessment. Two participants who were MG Composite responders at Month 3 were lost to follow-up after their Month 3 assessments and were not assessed in the follow-up portion of the treatment.

Deepening responses were observed over time, with participants included in the primary efficacy dataset (n=12) experiencing an average MG-ADL reduction of 5.5 (±1.1) at Month 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 were observed to further deepen at Month 6, with 33% (4/12) of participants in the primary efficacy dataset and 57% (4/7) of participants with no prior exposure to biologic therapy observed to have minimum symptom expression, defined as an MG-ADL score of 0 or 1. Responses were observed to be durable through Month 12, with 80% (4/5) 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 two participants with no prior exposure to biologic therapy that reached Month 12, both maintained at least a clinically meaningful response, with one continuing to demonstrate minimum symptom expression.

Descartes-08 continues to be observed as well-tolerated, supporting outpatient administration without the need for lymphodepleting chemotherapy. Consistent with previously reported data, Descartes-08 was observed to be well-tolerated across the safety dataset (n=36), and adverse events were transient and mostly mild. Notably, there were no cases of cytokine release syndrome, and no cases of immune effector cell-associated neurotoxicity syndrome. In addition, treatment with Descartes-08 was not observed to lead to a decrease in vaccine titers for common viruses and was not associated with increased rates of infection or hypogammaglobulinemia.

	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%)					

Forward Looking Statements

Any statements in this Current Report on Form 8-K about the future expectations, plans and prospects of the Company, including without limitation, 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 Current Report on

Form 8-K 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 Current Report on Form 8-K, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press Release of Cartesian Therapeutics, Inc., dated December 3, 2024.
99.2	Cartesian Therapeutics, Inc. Phase 2b Updated Data Presentation.
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: December 3, 2024

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

Cartesian Therapeutics Announces Positive Updated Results from Phase 2b Trial of Descartes-08 in Participants with Myasthenia Gravis and Outlines Design of Planned Phase 3 Trial

Phase 3 AURORA trial on track to commence in 1H2025; Primary endpoint to assess proportion of Descartes-08-treated participants with myasthenia gravis demonstrating an MG-ADL improvement of ≥3 points at Month 4 relative to placebo

Deepening responses observed over time in Phase 2b trial, with Descartes-08-treated participants observed to have a 5.5-point reduction in MG-ADL at Month 4

Durable responses observed through Month 12 in Phase 2b trial

Safety profile consistent with previously reported data and continues to support outpatient administration

Company to host conference call and webcast with key opinion leader today at 7:30 a.m. ET

Frederick, MD, December 3, 2024 (GLOBE NEWSWIRE) – Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering mRNA cell therapy for autoimmune diseases, today announced updated efficacy and safety data from the Phase 2b trial of Descartes-08 in participants with generalized myasthenia gravis (MG) and provided details on the design of its planned Phase 3 AURORA trial. The updated data will be presented today at the 2nd Annual Cell Therapy for Autoimmune Disease Summit being held in Philadelphia.

Descartes-08, Cartesian's lead mRNA cell therapy candidate, is an autologous mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA CAR-T) product candidate targeting B-cell maturation antigen (BCMA). Descartes-08 is designed to be administered without preconditioning chemotherapy and does not use integrating vectors. Descartes-08 was previously granted Regenerative Medicine Advanced Therapy (RMAT) Designation and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of MG.

"Current standards of care are associated with broad immunosuppression and limited efficacy, and patients with MG, which is a rare and incurable autoimmune disorder, are in dire need of new treatment options," said James F. Howard Jr., M.D., Professor of Neurology, Medicine, and Allied Health at the University of North Carolina School of Medicine, and investigator in the Phase 2b trial. "These updated results continue to show deep responses durable for months after cessation of treatment in both heavily pre-treated participants and, notably, participants without prior exposure to biologic drugs, underscoring the potential for Descartes-08 to emerge as a meaningful addition to available MG treatments."

"Data reported today add to the growing body of evidence supporting the potential for Descartes-08 to provide deep and durable improvements for participants with MG in the convenient outpatient setting and without the need for preconditioning chemotherapy," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Importantly, we believe these updated results align well with the endpoints of our planned Phase 3 trial, strengthening our confidence in the design of the next phase of

Descartes-08's development. We look forward to commencing the trial during the first half of next year as we continue to work toward our mission to deliver this much-needed therapy to patients with MG."

Overview of Planned Phase 3 AURORA Trial

The Company today provided details on the design of its planned Phase 3 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 acetylcholine receptor autoantibody positive (AChR Ab+) MG. The primary endpoint will assess the proportion of Descartes-08 participants with an improvement in MG Activities of Daily Living (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 (MGC) score, as well as improvements in other validated MG severity scales, including Quantitative MG (QMG) and MG Quality of Life Revised Scale (MG-QoL-15R).

Cartesian expects to commence the trial in the first half of 2025.

Updated Phase 2b Trial Results

In the Phase 2b double-blind, placebo-controlled, crossover trial, a total of 36 heavily pre-treated, highly symptomatic participants with MG were randomized 1:1 to receive either Descartes-08 or placebo administered as six weekly outpatient infusions without preconditioning chemotherapy. As previously announced, the trial met its primary endpoint and demonstrated a safety profile supporting outpatient administration of Descartes-08.

The primary efficacy dataset for the follow-up portion of the trial consisted of a modified intent-to-treat (mITT) population of all subjects enrolled at academic medical centers who received at least one dose of Descartes-08 and completed at least one post-Month 3 MG-ADL score follow-up assessment. As of an October 31, 2024 cutoff date, 12 participants in the primary efficacy dataset completed their Month 4 and Month 6 follow-up assessments, with eight participants evaluable for their Month 9 assessment, and five participants evaluable for their Month 12 assessment. Two participants who were MGC responders at Month 3 were lost to follow-up after their Month 3 assessments and were not assessed in the follow-up portion of the treatment.

Updated Efficacy Results

- Deepening responses were observed over time, with participants included in the primary efficacy dataset (n=12) experiencing an average MG-ADL reduction of 5.5 (±1.1) at Month 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 (FcRn) inhibitors, with an average MG-ADL reduction of 6.6 (±1.5).
- Responses were observed to further deepen at Month 6, with 33% (4/12) of participants in the primary efficacy dataset and 57% (4/7) of participants with no prior exposure to biologic therapy observed to have minimum symptom expression, defined as an MG-ADL score of 0 or 1.

- Responses were observed to be durable through Month 12, with 80% (4/5) 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 two participants with no prior exposure to biologic therapy that reached Month 12, both maintained at least a clinically meaningful response, with one continuing to demonstrate minimum symptom expression.

Safety

- Descartes-08 continues to be observed as well-tolerated, supporting outpatient administration without the need for lymphodepleting chemotherapy. Consistent with previously reported data, Descartes-08 was observed to be well-tolerated across the safety dataset (n=36), and adverse events were transient and mostly mild. Notably, there were no cases of cytokine release syndrome (CRS), and no cases of immune effector cell-associated neurotoxicity syndrome (ICANS). In addition, treatment with Descartes-08 was not observed to lead to a decrease in vaccine titers for common viruses and was not associated with increased rates of infection or hypogammaglobulinemia.

Updated Phase 2a Open-Label Trial Results

Cartesian today also announced positive updated results from retreated participants enrolled in the Phase 2a open-label portion of the trial. Two participants were previously retreated, and experienced rapid improvement in clinical scores and maintained minimum symptom expression for up to one year after receiving a second treatment cycle. A third participant received a second treatment cycle and at the participant's Month 2 visit, two weeks after the last Descartes-08 infusion, achieved a 4-point reduction in MG-ADL and 6-point reduction in MGC scores from baseline, without reports of CRS or ICANS. The time course and magnitude of treatment response upon retreatment were similar to the time course and magnitude of treatment response observed when the participants were first treated. Four of the seven remaining participants from the Phase 2a portion of the trial maintained clinically meaningful responses for at least one year following initial dosing.

The Company previously announced positive long-term follow up data from the Phase 2a trial in which Descartes-08 was administered in an outpatient setting without preconditioning chemotherapy. Durable depletion of autoantibodies and clinically meaningful improvements in MG severity scores were observed at the one-year follow-up period. The data were subsequently featured during an oral session at the American Society of Gene and Cell Therapy 27th Annual Meeting in May 2024.

Conference Call and Webcast

The Company will host a conference call and webcast to discuss the updated data, as well as the design of its planned Phase 3 trial today, Tuesday, December 3, 2024, at 7:30 a.m. ET. Joining members of the Cartesian management team will be Dr. Howard.

To access the conference call, please dial 1-800-715-9871 (toll-free) or 1-646-307-1963 (international) at least 10 minutes prior to the start time and ask to be joined into the Cartesian Therapeutics call. The live audio webcast, along with accompanying slides, can be accessed on the Events & Presentations section

of Cartesian's website at https://ir.cartesiantherapeutics.com/news-and-events/events-presentations. A replay of the webcast will be available for a limited time following the event on Cartesian's website.

About Myasthenia Gravis

Myasthenia gravis (MG) is a chronic autoimmune disorder that causes disabling muscle weakness and fatigue. For most people with MG, the disease is characterized by the presence of antibodies against the acetylcholine receptor, a protein found on the surface of nerve cells that plays a key role in muscle contraction. There is currently no cure for MG, and treatment typically requires chronic immunosuppressive medicines, with their attendant risks and side effects.

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 Cartesian Therapeutics

Cartesian Therapeutics is a clinical-stage company pioneering mRNA cell therapies 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

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Investor Contact

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Media Contact

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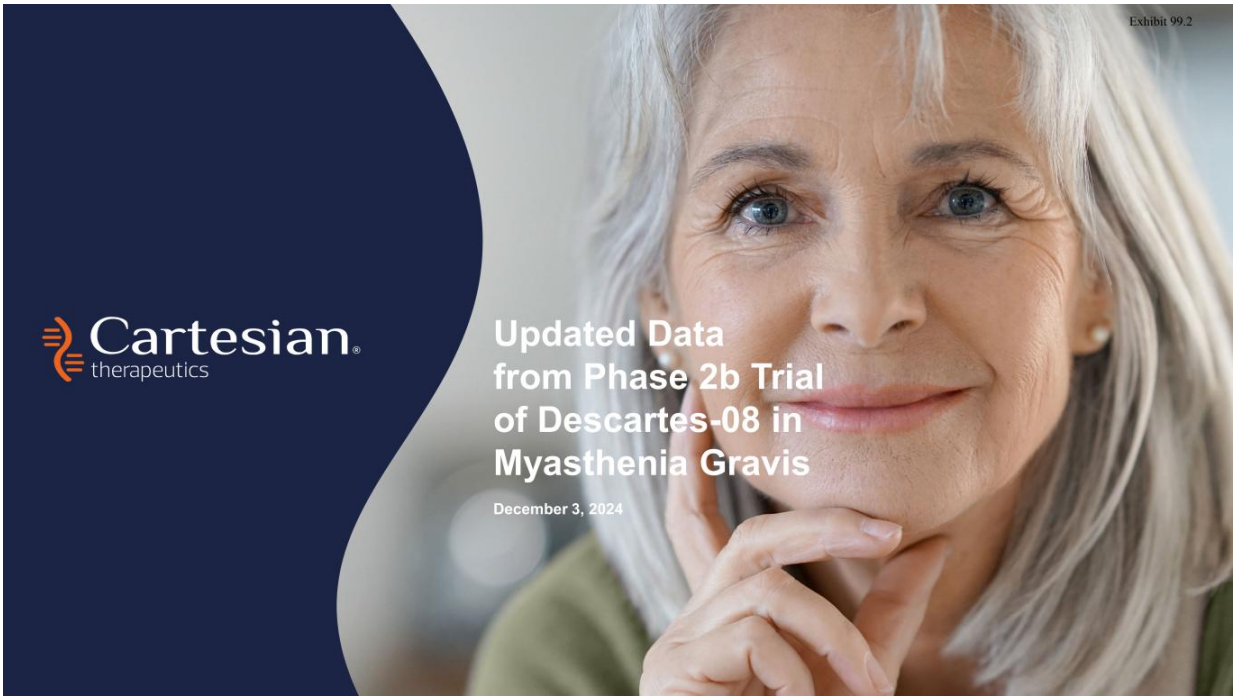
Exhibit 99.2


Cartesian
therapeutics
Updated Data
from Phase 2b Trial
of Descartes-08 in
Myasthenia Gravis
December 3, 2024

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.

Forward-looking Statements

Any statements in this presentation about the future expectations, plans and prospects of the Company, including without limitation, 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.

Call participants

Carsten Brunn, PhD
PRESIDENT AND CEO

Miloš Miljković, MD
CHIEF MEDICAL OFFICER

Blaine Davis
CHIEF FINANCIAL OFFICER

James F. Howard Jr., MD
PROFESSOR OF NEUROLOGY, MEDICINE, AND ALLIED HEALTH
UNIVERSITY OF NORTH CAROLINA SCHOOL OF MEDICINE

Deep and durable response maintained over 12 months in participants treated with Descartes-08

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

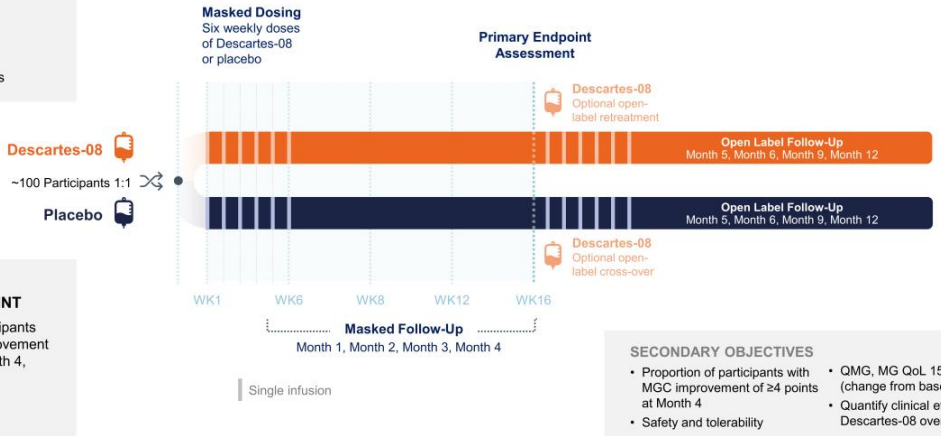
- Primary endpoint to assess MG-ADL improvement of ≥3 points at Month 4 relative to placebo
- Expected to commence in 1H25

MG-ADL, Myasthenia Gravis Activities of Daily Living scale
U.S. FDA, United States Food and Drug Administration

AURORA: Randomized double-blind, placebo-controlled Phase 3 trial of Descartes-08 in AChR Ab+ gMG

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

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

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

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

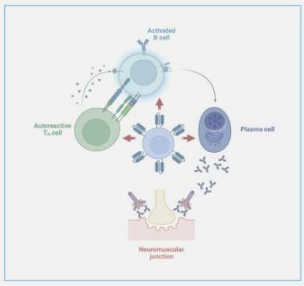
Does not carry risk of genomic integration

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



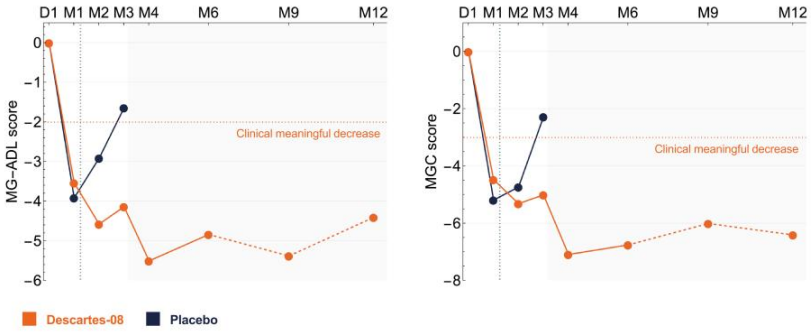
RMAT, Regenerative Medicine Advanced Therapy
RPDD, Rare Pediatric Disease Designation

BCMA, B-cell maturation antigen
CAR, Chimeric antigen receptor

Cartesian therapeutics

Deepening responses observed in participants treated with Descartes-08

Primary Efficacy Dataset



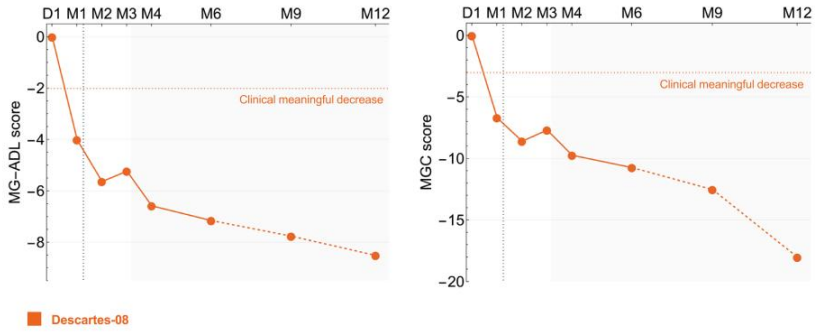
Month 3 (n=14), Month 4 (n=12*), Month 6 (n=12), Month 9 (n=8), Month 12 (n=5)
**Two participants lost to follow-up*

- 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

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Safety profile continues to support 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%)					

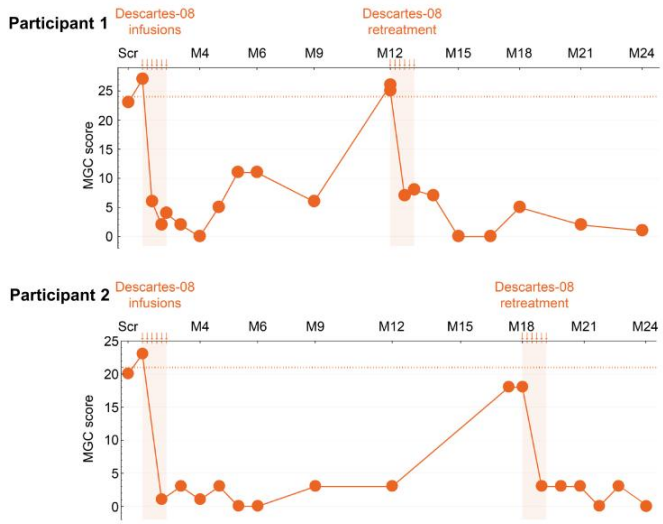
- **No new type of AEs reported**
- **No hypogammaglobulinemia or increased infections reported**
- **No difference in vaccine titers between Descartes-08 and placebo**

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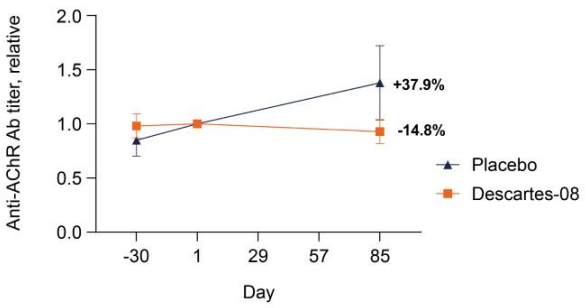
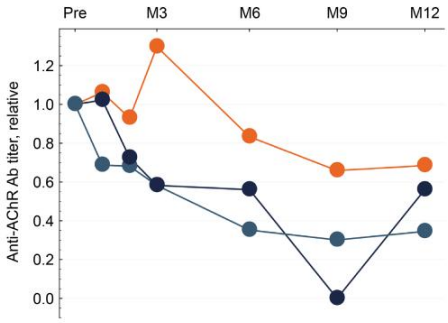
Approximately 15% reduction in AChR antibody titer at Month 3 is in line with Phase 2a data



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

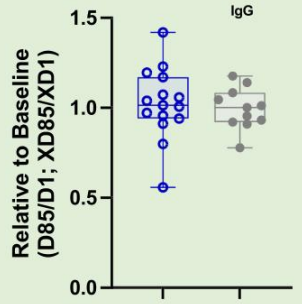


Individual Anti-AChR antibody titers in all participants receiving six once-weekly infusions in the Phase 2a trial with detectable baseline levels (n=3).

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

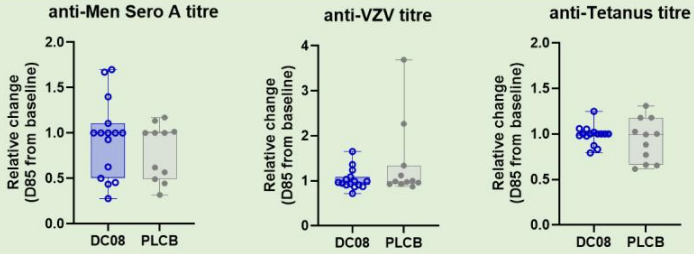
Descartes-08 observed not to deplete broader antibody repertoire or decrease vaccine titers for common viruses

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

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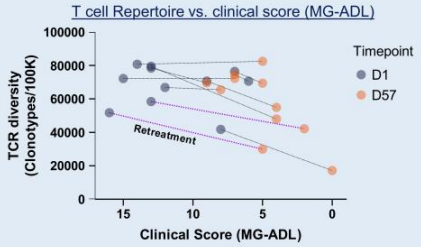
Descartes-08 focuses the T-cell repertoire and selectively alters the autoreactome, showing clear biological activity

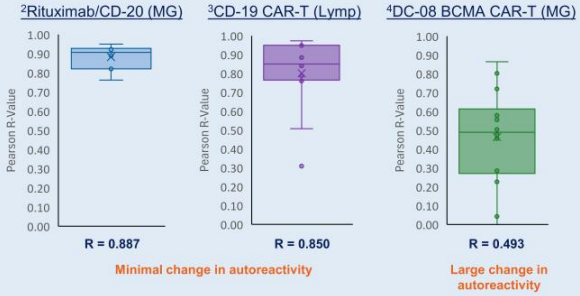
Descartes-08 focuses the T-cell repertoire in a manner that correlates with clinical effect



p=0.048 (Wilcoxon signed rank test) TCR Diversity D57 vs D1

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

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

cGMP, Current good manufacturing practice

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Deep and durable response maintained over 12 months in participants treated with Descartes-08

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

Q&A

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