

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): September 29, 2026

CARTESIAN THERAPEUTICS, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-37798  
(Commission  
File Number)

26-1622110  
(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 September 29, 2026, Cartesian Therapeutics, Inc. (the “Company”) issued a press release announcing additional retreatment data from the Company’s Phase 2 trial of Descartes-08 in patients with myasthenia gravis (“MG”). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

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 8.01 Other Events.

On September 29, 2026, the Company announced additional retreatment data from the Company’s Phase 2 trial of Descartes-08 in patients with MG. The data consisted of observations from five participants who experienced recurrence of MG symptoms (as measured by Myasthenia Gravis Activities of Daily Living (“MG-ADL”) ≥6) following 12-month follow-up from the initial course of Descartes-08 treatment in the Phase 2 trial. Key observations included:

Efficacy

- Patients retreated at a median of 16.6 months following completion of initial treatment course experienced greater improvement in MG symptoms compared to initial course of treatment; mean decrease in MG-ADL scores were sustained through 12 months following retreatment
  - Retreated patients observed an average MG-ADL reduction of 6.6 (±4.2) points from baseline at Month 12.
  - Retreated patients observed an average Myasthenia Gravis Composite (“MGC”) reduction of 15 (±6.2) points from baseline at Month 12.
  - All retreated patients experienced a clinically meaningful reduction across MGC (≥3-point reduction) and MG-ADL scores (≥2-point reduction), and four patients maintained the clinically meaningful MG-ADL reduction through Month 12 following retreatment.

Safety

- Consistent safety data observed to date supports potential retreatment of Descartes-08 following recurrence of MG symptoms, as clinical benefit was observed with no new safety concerns
  - Descartes-08 was observed to be generally well-tolerated through Month 12 following retreatment, and adverse events were transient and mild. No serious adverse events were reported during retreatment. Notably, there were no cases of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, cytopenias, or hypogammaglobulinemia.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Exhibit Description                                                                         |
|-------------|---------------------------------------------------------------------------------------------|
| 99.1        | <a href="#">Press release of Cartesian Therapeutics, Inc. issued on September 29, 2026.</a> |
| 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.

Date: September 29, 2026

CARTESIAN THERAPEUTICS, INC.

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

## **Cartesian Therapeutics Announces Additional Retreatment Data for Descartes-08 Highlighting Deep and Durable Responses in Patients with Myasthenia Gravis**

*Descartes-08 demonstrated improvement in mean change from baseline in MG-ADL following initial treatment and retreatment; mean MG-ADL reduction of 6.6 points at Month 12 following retreatment*

*Median interval between end of initial treatment course and first retreatment infusion was 16.6 months*

*No new safety signals reported; safety profile consistent with previously reported data*

*Topline data from Phase 3 AURORA trial of Descartes-08 in patients with myasthenia gravis expected in 1Q27*

FREDERICK, MD, September 29, 2026 (GLOBE NEWSWIRE) -- Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company" or "Cartesian"), a late clinical-stage biotechnology company pioneering cell therapy for autoimmune diseases, today announced additional positive retreatment data of its lead investigational asset, Descartes-08, in patients with generalized myasthenia gravis (MG), being presented today during the Myasthenia Gravis Foundation of America (MGFA) Scientific Session of the 2026 American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting being held in Orlando, Florida.

Descartes-08 is Cartesian's autologous anti-B cell maturation antigen (BCMA) chimeric antigen receptor T-cell therapy (CAR-T) in clinical development for MG and myositis. Dr. James F. Howard Jr., M.D., a distinguished neurologist at the University of North Carolina School of Medicine and investigator in the Phase 2b trial, will present the case series of five retreated patients who experienced clinically meaningful improvements in MG severity scores following a recurrence of MG symptoms at least 12 months after the initial course of Descartes-08 treatment.

"There remains a significant unmet need for patients suffering from MG today where current treatment options require patients to utilize chronic immunosuppressants to manage the disease," said James F. Howard, Jr., M.D., Cartesian Clinical Advisor and Professor of Neurology, Medicine, and Allied Health at the University of North Carolina School of Medicine. "Descartes-08 is designed to target BCMA+ immune cells in MG to potentially provide patients with sustained symptom improvement reflected in clinically significant MG-ADL reductions with the added ability to be re-dosed if symptoms recur. For patients who have already cycled through multiple therapies, the option to retreat a CAR-T cell therapy, in an outpatient setting and without lymphodepleting chemotherapy, represents an exciting potential advancement in the field of MG."

### **12-Month Retreatment Results**

The data presented today at AANEM analyzed the efficacy, safety, and durability of Descartes-08 retreatment in five patients with MG who previously received a full treatment course in the Phase 2 portion of the trial and experienced recurrence of symptoms (Myasthenia Gravis Activities of Daily Living [MG-ADL]  $\geq 6$ ) following 12-month follow-up. Similar to the initial course of treatment, retreatment consisted of six once-weekly Descartes-08 infusions. Clinical outcomes were assessed by mean change in Myasthenia Gravis Composite (MGC) and MG-ADL scores from baseline through Month 12. Safety and tolerability were also assessed across treatment courses. Patients had a mean disease duration of 13 years with extensive treatment histories.

#### *Efficacy*

- **Patients retreated (n=5) at a median of 16.6 months following completion of initial treatment course experienced greater improvement in MG symptoms compared to initial course of**

**treatment; mean decrease in MG-ADL scores were sustained through 12 months following retreatment**

- Retreated patients observed an average MG-ADL reduction of 6.6 ( $\pm 4.2$ ) points from baseline at Month 12.
- Retreated patients observed an average MGC reduction of 15 ( $\pm 6.2$ ) points from baseline at Month 12.
- All retreated patients experienced a clinically meaningful reduction across MGC ( $\geq 3$ -point reduction) and MG-ADL scores ( $\geq 2$ -point reduction), and four patients maintained the clinically meaningful MG-ADL reduction through Month 12 following retreatment.

**Safety**

- **Consistent safety data observed to date supports potential retreatment of Descartes-08 following recurrence of MG symptoms, as clinical benefit was observed with no new safety concerns**
  - Descartes-08 was observed to be generally well-tolerated through Month 12 following retreatment, and adverse events were transient and mild. No serious adverse events were reported during retreatment. Notably, there were no cases of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), cytopenias, or hypogammaglobulinemia.

“Descartes-08’s clinical data generated to date has demonstrated the potential for meaningful clinical responses that persist through 12 months following the completion of an initial course of treatment, with the ability to be re-dosed if needed. Unlike currently approved therapies that generally require cyclical dosing to maintain effect, Descartes-08 is being developed with the goal of providing sustained clinical benefit following a finite course of treatment,” said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. “We believe the combination of sustained symptom improvement, the ability to retreat if symptoms return, and the quality-of-life benefits of outpatient administration without lymphodepleting chemotherapy sets Descartes-08 apart and has the potential to meaningfully change the way MG is treated. These data strengthen our conviction in Descartes-08 as we approach topline results from our Phase 3 AURORA trial, expected in the first quarter of 2027.”

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. Cartesian received written agreement from the FDA under the Special Protocol Assessment (SPA) process indicating the overall design of the planned Phase 3 AURORA trial of Descartes-08 is acceptable to support a future biologics license application (BLA) in MG, subject to the ultimate outcome of the trial. Cartesian remains on track to readout topline data from its Phase 3 AURORA trial of Descartes-08 in MG in the first quarter of 2027, with a BLA filing expected in mid-2027.

**About Descartes-08**

Descartes-08, Cartesian’s lead cell therapy candidate, is an investigational, autologous CAR-T product targeting BCMA in clinical development for generalized MG and myositis, specifically dermatomyositis and antisynthetase syndrome. In contrast to conventional DNA-based CAR T-cell therapies, Cartesian’s 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 late clinical-stage company pioneering cell therapy for the treatment of autoimmune diseases. The Company's lead asset, Descartes-08, is a CAR-T in Phase 3 clinical development for patients with generalized myasthenia gravis, Phase 2 clinical development in myositis, specifically dermatomyositis and antisynthetase syndrome, and in Phase 1/2 clinical development for pediatric autoimmune diseases, including juvenile dermatomyositis. For more information, please visit [www.cartesiantherapeutics.com](http://www.cartesiantherapeutics.com) or follow the Company on [LinkedIn](#) or [X](#).

## Forward Looking Statements

Any statements in this press release about the future expectations, plans and prospects of the Company, including without limitation, 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, or any of the Company's other product candidates to treat MG, juvenile MG, myositis, juvenile dermatomyositis, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, including the ongoing Phase 3 AURORA trial of Descartes-08 in MG, the ongoing Phase 2 TRITON trial of Descartes-08 in myositis, and the ongoing Phase 1/2 HELIOS pediatric trial of Descartes-08 in autoimmune diseases, including juvenile dermatomyositis, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, including the number of trials that may be necessary in order to obtain marketing approval, the potential for in-vivo delivery of the Company's product candidates, 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 ability of the Company to enter into and maintain potential collaborations or partnerships, 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, pandemics, and macroeconomic impacts, 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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