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 27, 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 8.01. Other Information.

On January 27, 2025, Cartesian Therapeutics, Inc. (the "Company") issued a press release announcing that it has received written agreement from the U.S. Food and Drug Administration under the Special Protocol Assessment process on the overall design of the Company's Phase 3 AURORA trial for Descartes-08, its lead mRNA cell therapy candidate, in myasthenia gravis. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press release of Cartesian Therapeutics, Inc. issued on January 27, 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 27, 2025

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

Cartesian Therapeutics Announces FDA Special Protocol Assessment Agreement for Phase 3 AURORA Trial of Descartes-08 in Myasthenia Gravis

Trial on track to commence in 1H25

FREDERICK, Md., Jan. 27, 2025 (GLOBE NEWSWIRE) – Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering mRNA cell therapy for autoimmune diseases, today announced that it has received written agreement from the U.S. Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) process on the overall design of the Company's planned Phase 3 AURORA trial for Descartes-08, its lead mRNA cell therapy candidate, in myasthenia gravis (MG). The SPA agreement indicates that the FDA has determined that the proposed trial design is acceptable to support a future Biologics License Application for Descartes-08 in MG, subject to the ultimate outcome of the trial.

"This SPA agreement marks an important milestone in the development of Descartes-08 for MG, providing critical regulatory clarity and a clear path toward potential approval," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Supported by compelling Phase 2b results where we observed deep and durable improvements in patients with MG, we firmly believe that Descartes-08 has the potential to serve as a meaningful new therapy that can be delivered in the convenient outpatient setting without the need for preconditioning chemotherapy. We look forward to commencing the Phase 3 AURORA trial in the first half of this year."

The randomized, double-blind, placebo-controlled Phase 3 AURORA 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.
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.

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 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 planned Phase 3 AURORA trial, 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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