UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): March 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 2.02 Results of Operations and Financial Condition.

On March 13, 2025, Cartesian Therapeutics, Inc. (the "Company") announced its financial results for the year ended December 31, 2024. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Exhibit Description
99.1	Press release of Cartesian Therapeutics, Inc. issued on March 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: March 13, 2025

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

Exhibit 99.1

Cartesian Therapeutics Reports Full Year 2024 Financial Results and Provides Business Update

Phase 3 AURORA trial of Descartes-08 in myasthenia gravis on track to commence in 1H25; Deep and durable responses maintained over 12 months in Descartes-08-treated participants in Phase 2b trial

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

Company expects to initiate Phase 2 pediatric basket trial of Decartes-08 in select autoimmune indications in 2H25

Dosing underway in first-in-human Phase 1 trial of Descartes-15

Approximately $214.3 million cash, cash equivalents and restricted cash as of December 31, 2024 expected to support planned operations into mid-2027, including completion of planned Phase 3 AURORA trial

Frederick, MD, March 13, 2025 (GLOBE NEWSWIRE) – Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company"), a clinical-stage biotechnology company pioneering mRNA cell therapy for autoimmune diseases, today reported financial results for the full year ended December 31, 2024, and outlined recent corporate updates.

"Following a year marked by tremendous progress, we remain committed to advancing our pipeline of mRNA cell therapies designed to be dosed in the convenient outpatient setting, without the need for preconditioning chemotherapy," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Notably, we remain on track to commence our planned Phase 3 AURORA trial of Descartes-08 in patients with myasthenia gravis (MG) in the first half of this year. Supported by positive results from our Phase 2b trial demonstrating deep and durable improvements for Descartes-08-treated participants, along with our Special Protocol Assessment (SPA) agreement with U.S. Food and Drug Administration (FDA), we are confident that we have a clear path toward potential approval of this promising new therapy."

Dr. Brunn continued, "Beyond MG, we remain on track to report preliminary data from our ongoing Phase 2 open-label trial of Descartes-08 in patients with systemic lupus erythematosus (SLE) and expect to initiate our Phase 2 pediatric basket trial of Descartes-08 in select autoimmune diseases in the second half of this year. With these anticipated milestones, along with our strong balance sheet, we believe we are well-positioned to deliver on our mission to expand the reach of cell therapy to autoimmunity."

Recent Pipeline Progress and Anticipated Milestones

- **Phase 3 AURORA Trial of Descartes-08 in MG on Track to Commence in the First Half of 2025.** 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 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. Descartes-08, Cartesian's lead product candidate, is an autologous anti-B cell maturation antigen (BCMA) mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA CAR-T).

  In January 2025, Cartesian announced that it has received written agreement from the FDA under the SPA process on the overall design of the planned Phase 3 AURORA trial. 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.

- **Announced Positive Updated Results from Phase 2b Trial of Descartes-08 in Participants with MG, with Deepening Response Observed Over Time, Durable Through Month 12.** In December 2024, the Company announced updated efficacy and safety data from the Phase 2b trial of Descartes-08 in participants with MG.

Participants included in the primary efficacy dataset (n=12)[1] experienced an average MG-ADL reduction of 5.5 (±1.1) at Month 4. 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. Descartes-08 continues to be observed as well-tolerated, supporting outpatient administration without the need for lymphodepleting chemotherapy.

- **Dr. Tuan Vu, one of Cartesian's Clinical Advisors, will Present at the American Academy of Neurology Annual Meeting on April 9, 2025 at 1:12 pm PT**. The presentation and abstract are titled, "The Efficacy and Safety of Autologous BCMA-directed mRNA CAR T-Cell Therapy in Generalized Myasthenia Gravis: Results from a Phase 2b Randomized Placebo-controlled Trial."

- **Preliminary Data from Ongoing Phase 2 Open-Label Trial of Descartes-08 in Patients with SLE Expected in the Second Half of 2025.** The trial is designed to assess the safety, tolerability and clinical activity of outpatient Descartes-08 administration without preconditioning chemotherapy in patients with SLE. 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.

- **Phase 2 Pediatric Basket Trial of Descartes-08 in Select Autoimmune Diseases Expected to Initiate in the Second Half of 2025.** This pediatric basket trial will target juvenile SLE, juvenile MG, juvenile dermatomyositis (JDM) and anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis. The FDA previously granted Rare Pediatric Disease Designation to Descartes-08 for the treatment of JDM, which is a rare pediatric autoimmune disorder.

- **Dosing Ongoing in First-in-Human Phase 1 Clinical Trial of Descartes-15.** The Phase 1 dose escalation trial of Cartesian's next-generation, autologous anti-BCMA mRNA CAR-T cell therapy, 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.

Corporate Updates

- **Emily English Promoted to Chief Operations Officer.** Emily English, formerly Cartesian's Senior Vice President and Head of Manufacturing Operations, was promoted to Chief Operations Officer in January 2025. Emily's significant contributions, including her leadership in the expansion of the new, state-of-the-art current good manufacturing practice (cGMP) facility in Frederick, Maryland, have been instrumental in Cartesian's progress as the Company continues to advance its pipeline.

Full Year 2024 Financial Results

- Cash, cash equivalents and restricted cash as of December 31, 2024 was $214.3 million and is expected to support planned operations, including completion of planned Phase 3 AURORA trial for Descartes-08 in MG, into mid-2027.

- Research and development expenses were $45.1 million for the year ended December 31, 2024, compared to $71.3 million for the year ended December 31, 2023. The decrease was primarily a result of the Company's restructuring in 2023 prior to the merger between Cartesian and Selecta Biosciences, including reductions in expenses for preclinical and clinical programs due to the strategic reprioritization, stock compensation in connection with the Selecta Biosciences/ Cartesian Therapeutics merger, and higher expenses in 2023 compared to 2024 due to one-time cash charges related to salaries and benefits.

- General and administrative expenses were $30.1 million for the year ended December 31, 2024, compared to $40.5 million for the year ended December 31, 2023. The decrease in expense for the year ended December 31, 2024 was primarily the result of reductions in expenses incurred for stock compensation and professional fees in connection with the merger between Cartesian and Selecta Biosciences.

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[1] Primary efficacy dataset consisted of a modified intent-to-treat 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.

- Net loss was $(77.4) million, or $(4.48) net loss per share (basic), for the year ended December 31, 2024, compared to net loss of $(219.7) million, or $(49.76) net loss per share (basic), for the year ended December 31, 2023.

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 entering Phase 3 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. A Phase 3 trial of Descartes-08 in patients with generalized myasthenia gravis has received written agreement from the FDA under the Special Protocol Assessment process. The Company's clinical-stage pipeline also includes Descartes-15, a next-generation, autologous anti-BCMA mRNA CAR-T currently being evaluated in a Phase 1 trial in patients with multiple myeloma. 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 regarding the Company's expected cash resources and cash runway, the ability of the Company's product candidates to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the potential of Descartes-08, Descartes-15, or any of the Company's other product candidates to treat myasthenia gravis, juvenile myasthenia gravis, systemic lupus erythematosus, juvenile systemic lupus erythematosus, juvenile dermatomyositis, multiple myeloma, or any other disease, the amount and occurrence of any payments to holders of the Company's contingent value rights, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, including the planned Phase 3 AURORA trial of Descartes-08 in myasthenia gravis, the planned Phase 2 pediatric basket trial of Descartes-08 in juvenile dermatomyositis, juvenile systemic lupus erythematosus, juvenile myasthenia gravis and other conditions, and the ongoing Phase 2 trial of Descartes-08 in systemic lupus erythematosus, the anticipated timing or the outcome of the FDA's review of the Company's regulatory filings, the Company's ability to conduct its clinical trials and preclinical studies, the timing or making of any regulatory filings, the anticipated timing or outcome of selection of developmental product candidates, the novelty of treatment paradigms that the Company is able to develop, the potential of any therapies developed by the Company to fulfill unmet medical needs, and enrollment in the Company's clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "hypothesize," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including, but not limited to, the following: the uncertainties inherent in the initiation, completion and cost of clinical trials including proof of concept trials, including uncertain

outcomes, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results from a particular clinical trial will be predictive of the final results of that trial and whether results of early clinical trials will be indicative of the results of later clinical trials, the ability to predict results of studies performed on human beings based on results of studies performed on non-human subjects, the unproven approach of the Company's technology, potential delays in enrollment of patients, undesirable side effects of the Company's product candidates, political uncertainty, the Company's reliance on third parties to conduct its clinical trials, the Company's inability to maintain its existing or future collaborations, licenses or contractual relationships, its inability to protect its proprietary technology and intellectual property, potential delays in regulatory approvals, the availability of funding sufficient for its foreseeable and unforeseeable operating expenses and capital expenditure requirements, the Company's recurring losses from operations and negative cash flows, substantial fluctuation in the price of the Company's common stock, risks related to geopolitical conflicts and pandemics and other important factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and subsequently filed Quarterly Reports on Form 10-Q, and in other filings that the Company makes with the Securities and Exchange Commission. In addition, any forward-looking statements included in this 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.

Cartesian Therapeutics, Inc. and Subsidiaries

Consolidated Balance Sheets

(Amounts in thousands, except share data and par value)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 212,610	$ 76,911
Accounts receivable	872	5,870
Unbilled receivables	—	2,981
Prepaid expenses and other current assets	3,144	4,967
Total current assets	216,626	90,729
Non-current assets:		
Property and equipment, net	9,912	2,113
Right-of-use asset, net	5,535	10,068
In-process research and development assets	150,600	150,600
Goodwill	48,163	48,163
Long-term restricted cash	1,669	1,377
Investments	2,000	2,000
Other assets	518	—
Total assets	$ 435,023	$ 305,050
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 288	$ 3,150
Accrued expenses and other current liabilities	12,076	15,572
Lease liability	2,851	2,166
Deferred revenue	—	2,311
Warrant liabilities	—	720
Contingent value right liability	7,761	15,983
Forward contract liabilities	—	28,307
Total current liabilities	22,976	68,209
Non-current liabilities:		
Lease liability, net of current portion	11,133	8,789
Deferred revenue, net of current portion	—	3,538
Warrant liabilities, net of current portion	3,836	5,674
Contingent value right liability, net of current portion	387,739	342,617
Deferred tax liabilities, net	16,141	15,853
Total liabilities	441,825	444,680
Series A Preferred Stock, $0.0001 par value; no and 548,375 shares authorized as of December 31, 2024 and December 31, 2023, respectively; no and 435,120.513 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	296,851
Options for Series A Preferred Stock	—	3,703
Stockholders' deficit:		
Series A Preferred Stock, $0.0001 par value; 134,904.563 and no shares authorized as of December 31, 2024 and December 31, 2023, respectively; 120,790.402 and no shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Series B Preferred Stock, $0.0001 par value; 437,927 and no shares authorized as of December 31, 2024 and December 31, 2023, respectively; 437,927 and no shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	—	—
Preferred stock, $0.0001 par value; 9,427,168.437 and 9,451,625 shares authorized as of December 31, 2024 and December 31, 2023, respectively; no shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 25,767,369 and 5,397,597 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	3	1
Additional paid-in capital	689,887	179,062
Accumulated deficit	(692,071)	(614,647)
Accumulated other comprehensive loss	(4,621)	(4,600)
Total stockholders' deficit	(6,802)	(440,184)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 435,023	$ 305,050

Cartesian Therapeutics, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss

(Amounts in thousands, except share and per share data)

	Twelve Months Ended December 31,	
	2024	**2023**
Revenue:		
Collaboration and license revenue	$ 38,275	$ 26,004
Grant revenue	638	—
Total revenue	38,913	26,004
Operating expenses:		
Research and development	45,105	71,260
General and administrative	30,126	40,450
Impairment of long-lived assets	7,579	710
Total operating expenses	82,810	112,420
Operating loss	(43,897)	(86,416)
Interest income	7,386	4,964
Foreign currency transaction, net	—	38
Interest expense	—	(2,833)
Change in fair value of warrant liabilities	2,558	12,746
Change in fair value of contingent value right liability	(36,900)	(18,300)
Change in fair value of forward contract liabilities	(6,890)	(149,600)
Other income, net	606	691
Loss before income taxes	(77,137)	(238,710)
Income tax (expense) benefit	(287)	19,000
Net loss	$ (77,424)	$ (219,710)
Other comprehensive loss:		
Foreign currency translation adjustment	(21)	(53)
Unrealized gain on marketable securities	—	11
Total comprehensive loss	$ (77,445)	$ (219,752)
Net loss per share allocable to common stockholders:		
Basic	$ (4.48)	$ (49.76)
Diluted	$ (4.49)	$ (49.76)
Weighted-average common shares outstanding:		
Basic	17,276,822	5,170,319
Diluted	17,357,943	5,170,319

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