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): August 7, 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 August 7, 2025, Cartesian Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2025. 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 August 7, 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: August 7, 2025

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

Exhibit 99.1

Cartesian Therapeutics Reports Second Quarter 2025 Financial Results and Provides Business Update

Initiated Phase 3 AURORA trial of Descartes-08 in myasthenia gravis
Preliminary data from Phase 2 trial of Descartes-08 in systemic lupus erythematosus expected in 2H25

Initiation of Phase 2 pediatric basket trial of Descartes-08 in select autoimmune indications expected in 2H25

Approximately $162.1 million cash, cash equivalents and restricted cash as of June 30, 2025, expected to support planned operations into mid-2027, including completion of ongoing Phase 3 AURORA trial

Frederick, Md., August 7, 2025 (GLOBE NEWSWIRE) – Cartesian Therapeutics, Inc. (NASDAQ: RNAC) (the "Company" or "Cartesian"), a clinical-stage biotechnology company pioneering cell therapy for autoimmune diseases, today reported financial results for the second quarter ended June 30, 2025, and outlined recent corporate updates.

"Following the recent initiation of our pivotal Phase 3 AURORA trial of Descartes-08 in myasthenia gravis (MG), we have entered the second half of the year with significant momentum as we continue to advance our mission to deliver transformative cell therapies to patients with autoimmune diseases," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Supported by deep and sustained responses observed through month 12 in the Phase 2b trial along with a clearly defined regulatory pathway, we believe that, if approved, Descartes-08 has the potential to serve as an impactful new MG therapy with the ability to be safely dosed in the outpatient setting and without the need for preconditioning chemotherapy. Additionally, we continue to make progress advancing the balance of our programs and remain on track to share preliminary data from our ongoing Phase 2 trial of Descartes-08 in patients with systemic lupus erythematosus (SLE) and to initiate a pediatric basket trial in select autoimmune indications by the end of this year."

Recent Pipeline Progress and Anticipated Milestones

- **Initiated Phase 3 AURORA Trial of Descartes-08 in Participants with MG.** In May 2025, the Company announced that the first participant had been enrolled in the Phase 3 AURORA trial. The randomized, double-blind, placebo-controlled Phase 3 AURORA trial is designed to assess Descartes-08, Cartesian's autologous anti-B cell maturation antigen (BCMA) chimeric antigen receptor T-cell therapy (CAR-T) 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.

  In April 2025, the Company announced updated efficacy and safety data from the Phase 2b trial of Descartes-08 in participants with MG. After a single course of therapy, Descartes-08-treated participants were observed to sustain deep responses through long-term follow-up, with an average 4.8-point reduction in the MG-ADL score at Month 12. The deepest and most compelling sustained responses were observed in Descartes-08-treated participants who did not have prior exposure to biologic therapies, with an average 7.1-point reduction in MG-ADL score and 57% of patients in this subgroup maintaining minimum symptom expression at Month 12. The safety profile of Descartes-08 was consistent with previously reported data and continues to support outpatient administration.

  An encore presentation of the data, which were originally shared at the 2025 American Academy of Neurology Annual Meeting, was featured during the 15th International Conference on Myasthenia Gravis and Related Disorders on May 15, 2025 in The Hague, Netherlands.

- **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 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 is On Track 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 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.

Second Quarter 2025 Financial Results

- Cash, cash equivalents and restricted cash as of June 30, 2025 was $162.1 million and is expected to support planned operations, including completion of the ongoing Phase 3 AURORA trial for Descartes-08 in MG, into mid-2027.

- Research and development expenses were $14.9 million for the three months ended June 30, 2025, compared to $12.7 million for the three months ended June 30, 2024. The increase in expenses was primarily a result of increased expenses associated with the ongoing Phase 3 AURORA trial for Descartes-08 for MG.

- General and administrative expenses were $7.2 million for the three months ended June 30, 2025, compared to $7.0 million for the three months ended June 30, 2024. The increase in expenses was primarily the result of increased facilities expenses.

- Net income was $15.9 million, or $0.51 net income per share allocable to common stockholders (basic), for the three months ended June 30, 2025, compared to net income of $13.8 million, or $0.58 net income per share allocable to common stockholders (basic), for the three months ended June 30, 2024.

About Descartes-08

Descartes-08, Cartesian's lead cell therapy candidate, is an autologous chimeric antigen receptor T-cell therapy (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, 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 Descartes-15

Descartes-15 is a next-generation, autologous anti-BCMA 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 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 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 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, anti-neutrophil cytoplasmic antibody-associated vasculitis, multiple myeloma, or any other disease, the anticipated timing or the outcome of ongoing and planned clinical trials, studies and data readouts, including the 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 anti-neutrophil cytoplasmic antibody-associated vasculitis, 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, 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.

Cartesian Therapeutics, Inc. and Subsidiaries

Consolidated Balance Sheets

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

	June 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 160,324	$ 212,610
Accounts receivable	354	872
Prepaid expenses and other current assets	2,717	3,144
Total current assets	163,395	216,626
Non-current assets:		
Property and equipment, net	12,285	9,912
Right-of-use asset, net	5,164	5,535
In-process research and development assets	150,600	150,600
Goodwill	48,163	48,163
Long-term restricted cash	1,735	1,669
Investments	2,000	2,000
Other assets	5,551	518
Total assets	$ 388,893	$ 435,023
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 454	$ 288
Accrued expenses and other current liabilities	8,012	12,076
Lease liability	3,790	2,851
Contingent value right liability	—	7,761
Total current liabilities	12,256	22,976
Non-current liabilities:		
Lease liability, net of current portion	9,559	11,133
Warrant liabilities, net of current portion	1,364	3,836
Contingent value right liability, net of current portion	352,100	387,739
Deferred tax liabilities, net	16,141	16,141
Total liabilities	391,420	441,825
Stockholders' deficit:		
Series A Preferred Stock, $0.0001 par value; 134,904.563 shares authorized as of June 30, 2025 and December 31, 2024; 120,790.402 shares issued and outstanding as of June 30, 2025 and December 31, 2024	—	—
Series B Preferred Stock, $0.0001 par value; 437,927 shares authorized as of June 30, 2025 and December 31, 2024; 437,927 shares issued and outstanding as of June 30, 2025 and December 31, 2024	—	—
Preferred stock, $0.0001 par value; 9,427,168.437 shares authorized as of June 30, 2025 and December 31, 2024; no shares issued and outstanding as of June 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized as of June 30, 2025 and December 31, 2024; 26,000,065 and 25,767,369 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	3	3
Additional paid-in capital	695,942	689,887
Accumulated deficit	(693,895)	(692,071)
Accumulated other comprehensive loss	(4,577)	(4,621)
Total stockholders' deficit	(2,527)	(6,802)
Total liabilities and stockholders' deficit	$ 388,893	$ 435,023

Cartesian Therapeutics, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Income (Loss)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
		(Unaudited)		
Revenue:				
Collaboration and license revenue	$ —	$ 33,271	$ 400	$ 39,111
Grant revenue	298	174	998	174
Total revenue	298	33,445	1,398	39,285
Operating expenses:				
Research and development	14,869	12,661	29,543	22,399
General and administrative	7,240	7,027	15,555	16,477
Total operating expenses	22,109	19,688	45,098	38,876
Operating (loss) income	(21,811)	13,757	(43,700)	409
Interest income	1,748	1,195	3,763	2,359
Change in fair value of warrant liabilities	654	(3,908)	2,472	(2,866)
Change in fair value of contingent value right liability	35,300	2,500	35,646	(36,800)
Change in fair value of forward contract liabilities	—	—	—	(6,890)
Other (expense) income, net	(5)	292	(5)	800
Net income (loss)	$ 15,886	$ 13,836	$ (1,824)	$ (42,988)
Other comprehensive income:				
Foreign currency translation adjustment	12	14	44	9
Total comprehensive income (loss)	$ 15,898	$ 13,850	$ (1,780)	$ (42,979)
Net income (loss) per share allocable to common stockholders:				
Basic	$ 0.51	$ 0.58	$ (0.07)	$ (3.88)
Diluted	$ 0.50	$ 0.54	$ (0.07)	$ (3.88)
Weighted-average common shares outstanding:				
Basic	25,980,262	16,723,479	25,941,670	11,068,749
Diluted	26,447,251	17,791,143	25,941,670	11,068,749

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