

**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 7, 2024

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.)

704 Quince Orchard Road, Gaithersburg, MD 20878
(Address of principal executive offices)(Zip Code)

(617) 923-1400
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 7, 2024, Cartesian Therapeutics, Inc. announced its financial results for the year ended December 31, 2023. 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 contained 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 provided 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. dated March 7, 2024
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 7, 2024

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

Cartesian Therapeutics Reports Full Year 2023 Financial Results and Provides Business Update

Topline data from Phase 2b study of Descartes-08, the Company's potential first-in-class mRNA CAR-T cell therapy, in myasthenia gravis (MG) remains on track for mid-2024

On track to initiate Phase 2 study of Descartes-08 in systemic lupus erythematosus (SLE) in 1H24 as well as Phase 2 basket studies in additional autoimmune indications in 2H24

Following recent IND clearance, planning underway for first-in-human Phase 1 dose escalation study of Descartes-15, a next-generation mRNA CAR-T product candidate

Approximately \$118.3M pro forma cash, cash equivalents, and restricted cash as of December 31, 2023, expected to support planned operations into second half of 2026

GAITHERSBURG, MD, March 7, 2024 (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, 2023, and recent corporate updates.

"With several potentially value-creating milestones anticipated throughout the year ahead, we are making strong progress in our mission to deliver innovative cell therapies to patients suffering from autoimmune diseases," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "For our lead product candidate, Descartes-08, we continue to expect to report topline data from the ongoing Phase 2b trial in patients with myasthenia gravis (MG) mid-year. We believe this represents the most advanced and only randomized, controlled Phase 2 trial of a chimeric antigen receptor (CAR) T-cell therapy for autoimmune diseases."

Dr. Brunn continued, "Beyond MG, we continue to expect to initiate a Phase 2 study in patients with systemic lupus erythematosus (SLE) in the first half of the year. Supported by the clinical dataset from the previously completed Phase 2a study in patients with MG, we believe that Descartes-08, which we engineer with our novel mRNA engineered CAR-T (mRNA CAR-T) technology, does not require preconditioning chemotherapy, and is expected to be administered in an outpatient setting, could serve as the first CAR-T cell therapy to reach patients with autoimmune diseases."

Recent Pipeline Progress and Anticipated Milestones

- **Topline Data from Randomized Phase 2b Study of Descartes-08 in Patients with MG Expected for Mid-2024.** Enrollment remains ongoing in the Company's Phase 2b randomized, double-blind, placebo-controlled trial of Descartes-08 in patients with MG (NCT04146051), with topline results expected in mid-2024.
- **Announced Positive Long-Term Follow-Up Data from Phase 2a Study of Descartes-08 in Patients with MG.** In January 2024, Cartesian [announced](#) positive twelve-month follow-up data from its Phase 2a study of Descartes-08, the Company's autologous anti-B cell maturation antigen (BCMA) mRNA CAR-T cell therapy product candidate, in patients with generalized MG, a chronic autoimmune disorder that causes disabling muscle weakness and fatigue. In this study, Descartes-08 was administered in an outpatient setting without integrating vectors or preconditioning chemotherapy, and durable depletion of autoantibodies and clinically meaningful improvements in MG severity scores during the one-year follow-up period were observed. Descartes-08 was observed to be well-tolerated, with no dose-limiting toxicities, cytokine release syndrome, or neurotoxicity.

Descartes-08 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of MG.

- **Initiation of Phase 2 Study of Descartes-08 in Patients with SLE Expected for First Half of 2024.** The Company expects to initiate a Phase 2 study of Descartes-08 in patients with SLE (NCT06038474) in the first half of 2024. The Phase 2 study, for which the Company has received investigational new drug (IND) clearance, is designed to assess the safety and tolerability of outpatient Descartes-08 administration without preconditioning chemotherapy. SLE is an incurable autoimmune disease marked by systemic inflammation that affects multiple organ systems. It is estimated to impact approximately 1.5 million people in the United States.
- **IND Application Cleared for Descartes-15.** In January 2024, Cartesian announced that the FDA cleared its IND application for Descartes-15, a next-generation, autologous anti-BCMA mRNA CAR-T product candidate. As with Descartes-08, Descartes-15 is designed not to require preconditioning chemotherapy, has been observed to have predictable and controllable pharmacokinetics and is designed to avoid the risk of genomic integration. Planning for the first-in-human Phase 1 dose escalation study is underway. The study is designed to assess the safety and tolerability of outpatient Descartes-15 administration in patients with multiple myeloma. The Company expects to subsequently assess Descartes-15 in autoimmune indications.

Corporate Update

- **Upcoming Special Meeting of Stockholders Seeking to Approve Preferred Stock Conversion and Reverse Stock Split.** Cartesian plans to hold a special meeting of stockholders on March 27, 2024 to seek stockholder approval for the conversion of the Company's Series A Non-Voting Convertible Preferred Stock into the Company's common stock and a reverse stock split at a ratio in the range of 1-for-20 and 1-for-30. The reverse stock split would impact all holders of Cartesian common stock proportionally and would not impact any stockholder's percentage ownership of common stock. Holders of common stock of record as of February 13, 2024 are eligible to vote at the meeting.
- **Announced Plans to Transition Corporate Headquarters to Frederick, Maryland.** The Company recently [announced](#) plans to transition its corporate headquarters to Frederick, Maryland. The approximately 20,000 square foot state-of-the-art current good manufacturing practice (cGMP) compliant facility has clinical and commercial manufacturing scale capabilities designed to support the Company's maturing pipeline.
- **Completed Merger with Selecta Biosciences, Inc. and Concurrent \$60.25 Million Private Financing.** In November 2023, Cartesian [announced](#) its merger with Selecta Biosciences, Inc., creating a fully integrated, publicly traded company pioneering mRNA cell therapy for the treatment of autoimmune diseases. In connection with the merger, Cartesian announced a \$60.25 million private financing led by Timothy A. Springer, Ph.D.

Full Year 2023 Financial Results

- Pro forma cash, cash equivalents, and restricted cash of approximately \$118.3 million as of December 31, 2023, which reflects net proceeds received in the first quarter of 2024 from the November 2023 financing. The Company's pro forma cash and cash equivalents as of December 31, 2023, is expected to support planned operations and the development of Cartesian's pipeline into the second half of 2026, through the Phase 3 study of lead candidate, Descartes-08.
- Research and development expenses were \$71.8 million for the year ended December 31, 2023, compared to \$72.4 million for the year ended December 31, 2022. The decrease in expense of \$0.6 million for the year ended December 31, 2023 was primarily due to reductions in expenses incurred for preclinical and clinical programs due to the strategic reprioritization partially offset by expenses incurred for stock compensation and personnel expenses.
- General and administrative expenses were \$40.6 million for the year ended December 31, 2023, compared to \$23.9 million for the year ended December 31, 2022. The increase in expense of \$16.7 million for the year ended December 31, 2023 was primarily due to expenses incurred for stock compensation, personnel expenses, and professional fees incurred in connection with the merger.

- Net loss was \$(219.7) million, or \$(1.66) net loss per share (basic/diluted), for the year ended December 31, 2023, compared to net income of \$35.4 million, or \$0.24 net income per share (basic), for the year ended December 31, 2022.

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 a potential first-in-class mRNA CAR-T in Phase 2b clinical development for patients with generalized myasthenia gravis. Additional Phase 2 studies are planned in systemic lupus erythematosus under an allowed IND, as well as basket trials 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 regarding the Company's expected cash resources and cash runway, the Company's estimated cash on hand, the conversion of the Company's Series A Non-Voting Convertible Preferred Stock, the Company's plans to conduct a reverse stock split pending stockholder approval, the Company's headquarters relocation, the Company's manufacturing capabilities and ability to supply necessary quantities of its product candidates for clinical trials and potential commercialization, the Company's ability to maintain control over its product quality and production, the potential of RNA Armory® to enable precision control and optimization of engineered cells for diverse cell therapies leveraging multiple modalities, the potential of Descartes-08 and Descartes-15 and the Company's other product candidates to treat myasthenia gravis, systemic lupus erythematosus, or any other disease, the anticipated initiation timing of planned clinical trials, 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 anticipated timing or outcome of selection of developmental product candidates, the ability of the Company to consummate any expected agreements and licenses and to realize the anticipated benefits thereof, 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, the Company's ability to enter into and maintain its strategic partnerships, 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 RNA Armory® 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.

Cartesian Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets
(Amounts in thousands, except share data and par value)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 76,911	\$ 106,438
Marketable securities	—	28,164
Accounts receivable	5,870	6,596
Unbilled receivables	2,981	3,162
Prepaid expenses and other current assets	4,967	3,778
Total current assets	90,729	148,138
Non-current assets:		
Property and equipment, net	2,113	2,794
Right-of-use asset, net	10,068	11,617
In-process research and development assets	150,600	—
Goodwill	48,163	—
Long-term restricted cash	1,377	1,311
Investments	2,000	2,000
Other assets	—	26
Total assets	\$ 305,050	\$ 165,886
Liabilities, convertible preferred stock, and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	\$ 3,150	\$ 316
Accrued expenses and other current liabilities	15,572	14,084
Loan payable	—	8,476
Lease liability	2,166	1,608
Deferred revenue	2,311	593
Warrant liabilities	720	—
Contingent value right liability	15,983	—
Forward contract liabilities	28,307	—
Total current liabilities	68,209	25,077
Non-current liabilities:		
Loan payable, net of current portion	—	17,786
Lease liability, net of current portion	8,789	10,055
Deferred revenue, net of current portion	3,538	—
Warrant liabilities, net of current portion	5,674	19,140
Contingent value right liability, net of current portion	342,617	—
Deferred tax liabilities, net	15,853	—
Total liabilities	444,680	72,058
Series A Preferred Stock, \$0.0001 par value; 548,375 and no shares authorized as of December 31, 2023 and December 31, 2022, respectively; 435,120,513 and no shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	296,851	—
Options for Series A Preferred Stock	3,703	—
Stockholders' (deficit) equity:		
Preferred stock, \$0.0001 par value; 9,451,625 and 10,000,000 shares authorized as of December 31, 2023 and December 31, 2022, respectively; no shares issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized as of December 31, 2023 and December 31, 2022; 161,927,821 and 153,042,435 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	16	15
Additional paid-in capital	179,047	493,308
Accumulated deficit	(614,647)	(394,937)
Accumulated other comprehensive loss	(4,600)	(4,558)
Total stockholders' (deficit) equity	(440,184)	93,828
Total liabilities, convertible preferred stock, and stockholders' (deficit) equity	\$ 305,050	\$ 165,886

Cartesian Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations and Comprehensive Income (Loss)
(Amounts in thousands, except share and per share data)

	Year Ended December 31,		
	2023	2022	2021
Collaboration and license revenue	\$ 26,004	\$ 110,777	\$ 85,077
Operating expenses:			
Research and development	71,839	72,377	68,736
General and administrative	40,581	23,862	20,938
Total operating expenses	<u>112,420</u>	<u>96,239</u>	<u>89,674</u>
Operating (loss) income	(86,416)	14,538	(4,597)
Investment income	4,964	2,073	44
Foreign currency transaction gain (loss), net	38	(22)	—
Interest expense	(2,833)	(3,031)	(2,844)
Change in fair value of warrant liabilities	12,746	20,882	(2,339)
Change in fair value of contingent value right liability	(18,300)	—	—
Change in fair value of forward contract liabilities	(149,600)	—	—
Other income, net	691	330	15
(Loss) income before income taxes	(238,710)	34,770	(9,721)
Income tax benefit (expense)	19,000	609	(15,966)
Net (loss) income	<u>\$ (219,710)</u>	<u>\$ 35,379</u>	<u>\$ (25,687)</u>
Other comprehensive (loss) income:			
Foreign currency translation adjustment	(53)	18	(2)
Unrealized gain (loss) on marketable securities	11	(10)	(1)
Total comprehensive (loss) income	<u>\$ (219,752)</u>	<u>\$ 35,387</u>	<u>\$ (25,690)</u>
Net (loss) income per share:			
Basic	\$ (1.66)	\$ 0.24	\$ (0.22)
Diluted	<u>\$ (1.66)</u>	<u>\$ 0.10</u>	<u>\$ (0.22)</u>
Weighted-average common shares outstanding:			
Basic	<u>155,109,561</u>	<u>144,758,555</u>	<u>114,328,798</u>
Diluted	<u>155,109,561</u>	<u>145,874,889</u>	<u>114,328,798</u>

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