Cartesian Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Update

November 7, 2024

Company expects to commence Phase 3 trial of Descartes-08 in patients with myasthenia gravis in 1H2025 following recent meeting with U.S. Food and Drug Administration

Presentation of updated efficacy and safety data from Phase 2b trial and Phase 3 trial design of Descartes-08 in patients with myasthenia gravis expected by year-end

Dosing underway in Phase 2 trial of Descartes-08 in patients with systemic lupus erythematosus

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

Approximately $220.9M of cash, cash equivalents, and restricted cash as of September 30, 2024 expected to support planned operations, including completion of planned Phase 3 trial of Descartes-08 for myasthenia gravis, into mid-2027

FREDERICK, Md., Nov. 07, 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 third quarter of 2024, and provided business and corporate updates.

"As we approach the end of what has been a year of tremendous progress for Cartesian, we remain focused on advancing our innovative pipeline as we strive toward our mission to extend the potential of cell therapy to patients with autoimmune diseases," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Notably, for our lead Descartes-08 program in MG, we expect to share additional data from our Phase 2b trial and the design of our upcoming Phase 3 trial by the end of the year. With a growing body of clinical evidence supporting the potential for Descartes-08 to serve as a meaningful addition to the MG treatment landscape, we are encouraged by our recent interaction with FDA regarding our plans for a Phase 3 program in MG and plan to initiate the trial in the first half of 2025."

Dr. Brunn continued, "In addition to our MG development program, enrollment remains ongoing in our Phase 2 trial of Descartes-08 in patients with SLE, and we also remain on track to file an IND application for a pediatric basket study of Descartes-08 by year-end. Beyond Descartes-08, enrollment also continues in our first-in-human Phase 1 trial of Descartes-15, our next-generation autologous anti-BCMA mRNA CAR-T product candidate."

Recent Pipeline Progress and Anticipated Milestones

Descartes-08 in Generalized Myasthenia Gravis (MG)

- **Results from Phase 2b Trial of Descartes-08 in Patients with MG Featured at the 2024 Myasthenia Gravis Foundation of America (MGFA) Scientific Session of the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting.** In October 2024, data from the Company's Phase 2b trial of Descartes-08 in patients with MG were presented at the 2024 MGFA Scientific Session of the AANEM Annual Meeting. 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). Positive topline results were previously announced in July 2024, with the trial meeting its primary endpoint with statistical significance as 71% of MG patients treated with Descartes-08 were observed to have a clinically meaningful improvement in MG Composite score at Month 3 compared to 25% for placebo. In addition, Descartes-08 was observed to have a favorable safety profile supporting outpatient administration without the need for lymphodepleting chemotherapy.

  In addition to previously announced topline results, at Month 3, patients treated with Descartes-08 were observed to have a reduction in anti-acetylcholine receptor antibody titer levels, which is believed to be an early prognostic indicator for clinical improvement in patients with MG. Additionally, treatment with Descartes-08 was not observed to lead to a decrease in vaccine titers for common viruses and was not associated with increased rates of infection or hypogammaglobulinemia.

  The Company announced today that it plans to present updated efficacy and safety data from

the Phase 2b trial by year-end.

- **Planned Phase 3 Trial Expected to Commence in First Half of 2025 Following Recent Meeting with U.S. Food and Drug Administration (FDA).** Following a recent meeting with the FDA, the Company expects to commence its planned Phase 3 study of Descartes-08 in patients with MG in the first half of 2025. The Company plans to announce details regarding the trial design by year-end. Descartes-08 was previously granted Regenerative Medicine Advanced Therapy Designation and Orphan Drug Designation by the FDA for the treatment of MG.

- As previously announced, the Company's new corporate headquarters and approximately 30,000 square foot state-of-the-art current good manufacturing practice (cGMP) facility in Frederick, Maryland, is expected to support scaling of its wholly-owned, in-house cGMP manufacturing capabilities for the planned Phase 3 study in MG and commercial supply.

Descartes-08 in Systemic Lupus Erythematosus (SLE)

- **First Patient Dosed in Phase 2 Trial of Descartes-08 in SLE.** In July 2024, the Company announced dosing of the first patient in a Phase 2 open-label clinical trial evaluating Descartes-08 in SLE. 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.

Descartes-08 in Additional Indications

- **Rare Pediatric Disease Designation for Descartes-08 for the Treatment of Juvenile Dermatomyositis (JDM).** In September 2024, the Company announced that the FDA granted Rare Pediatric Disease Designation to Descartes-08 for the treatment of JDM. JDM is a rare pediatric autoimmune disorder marked by pathognomonic skin rash and muscle inflammation that affects multiple organ systems and impacts approximately 4,000 people in the United States. Under the FDA's Rare Pediatric Disease Designation and Voucher Program, if Descartes-08 is approved for marketing in JDM, Cartesian may qualify for a priority review voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product.

  By year-end 2024, the Company plans to file an investigational new drug (IND) application for a pediatric basket trial of Descartes-08 in certain autoimmune diseases, including JDM.

- **Safety and Tolerability Data to be Featured at 66th American Society of Hematology (ASH) Annual Meeting and Exposition.** In November 2024, the Company announced that safety and tolerability data from patients treated with Descartes-08 will be featured during a poster presentation at the upcoming 66th American Society of Hematology (ASH) Annual Meeting and Exposition, being held December 7-10, 2024, in San Diego.

Descartes-15 Program

- **First Patient Dosed in First-in-Human Phase 1 Trial of Descartes-15.** In September 2024, the Company announced dosing of the first patient in its first-in-human Phase 1 clinical trial evaluating Descartes-15, the Company's next-generation autologous anti-BCMA mRNA CAR-T product candidate. Descartes-15 is designed to be administered without

preconditioning chemotherapy, eliminating integrating vectors, and to have predictable and controllable pharmacokinetics, including technological advances that enhance CAR stability even in the presence of target-driven suppression of CAR. The Phase 1 dose escalation trial 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

- **Completed $130.0 Million Private Placement Equity Financing.** In July 2024, Cartesian announced a private investment in public equity (PIPE) financing, which included participation from both new and existing investors, resulting in gross proceeds of approximately $130.0 million.

- **Strengthened Board of Directors with Appointment of Kemal Malik.** In July 2024, the Company announced the appointment of Kemal Malik, MBBS to its Board of Directors. Dr. Malik's appointment provides regulatory and clinical expertise and deepens the Company's strategic leadership experience. Dr. Malik has over 30 years of global development, regulatory, and commercial experience at leading pharmaceutical organizations.

Third Quarter 2024 Financial Results

- Cash, cash equivalents, and restricted cash were approximately $220.9 million as of September 30, 2024. The Company's cash, cash equivalents, and restricted cash as of September 30, 2024 are expected to support planned operations into mid-2027 through completion of the planned Phase 3 clinical trial of Descartes-08 in MG, including anticipated manufacturing costs associated with the planned trial, the advancement and expansion of the Company's autoimmune pipeline, including Descartes-08 for SLE and other potential indications, and enhancements to the Company's process development and manufacturing capabilities.

- Research and development expenses were $11.4 million for the quarter ended September 30, 2024, compared to $13.0 million for the quarter ended September 30, 2023. The decrease in research and development expenses of $1.6 million for the quarter ended September 30, 2024, was due to reductions in clinical development expenses.

- General and administrative expenses were $6.6 million for the quarters ended September 30, 2024 and September 30, 2023, remaining consistent.

- Net loss was $(24.2) million, or $(1.13) basic net loss per share, for the quarter ended September 30, 2024, compared to net loss of $(9.0) million, or $(1.74) basic net loss per share, for the quarter ended September 30, 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 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 an mRNA CAR-T in Phase 2b clinical development for patients with generalized myasthenia gravis and Phase 2 development for systematic 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 regarding the Company's expectation to initiate a Phase 3 trial in myasthenia gravis in 2025, the Company's plan to release the myasthenia gravis Phase 3 trial design by the end of 2024, observations and data from the myasthenia gravis Phase 2b trial, the Company's expectation to share additional data from the Descartes-08 myasthenia gravis Phase 2b trial by the end of 2024, the Company's plan to file an IND application for a pediatric basket trial of Descartes-08 by the end of 2024, the ability of Descartes-08 or Descartes-15 to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the ability of Descartes-15 to have predictable and controllable pharmacokinetics, the likelihood of the Company qualifying for a priority review voucher and receiving priority review, the potential of the Company's technology to enable precision control and optimization of engineered cells for diverse cell therapies leveraging multiple modalities, 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, 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, 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, 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.

Cartesian Therapeutics, Inc. and Subsidiaries

Consolidated Balance Sheets

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

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 219,198	$ 76,911
Accounts receivable	4,829	5,870
Unbilled receivables	980	2,981
Prepaid expenses and other current assets	4,129	4,967
Total current assets	229,136	90,729
Non-current assets:		
Property and equipment, net	10,225	2,113
Right-of-use asset, net	13,523	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
Total assets	$ 455,316	$ 305,050
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 517	$ 3,150
Accrued expenses and other current liabilities	9,452	15,572
Lease liability	2,770	2,166
Deferred revenue	—	2,311
Warrant liabilities	5	720
Contingent value right liability	8,661	15,983
Forward contract liabilities	—	28,307
Total current liabilities	21,405	68,209

Non-current liabilities:		
Lease liability, net of current portion	11,881	8,789
Deferred revenue, net of current portion	—	3,538
Warrant liabilities, net of current portion	3,586	5,674
Contingent value right liability, net of current portion	401,839	342,617
Deferred tax liabilities, net	15,853	15,853
Total liabilities	454,564	444,680
Series A Preferred Stock, $0.0001 par value; no and 548,375 shares authorized as of September 30, 2024 and December 31, 2023, respectively; no and 435,120.513 shares issued and outstanding as of September 30, 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; 180,455.753 and no shares authorized as of September 30, 2024 and December 31, 2023, respectively; 166,341.592 and no shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Series B Preferred Stock, $0.0001 par value; 437,927 and no shares authorized as of September 30, 2024 and December 31, 2023, respectively; 437,927 and no shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Preferred stock, $0.0001 par value; 9,381,617.247 and 9,451,625 shares authorized as of September 30, 2024 and December 31, 2023, respectively; no shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 23,896,525 and 5,397,597 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	2	1
Additional paid-in capital	687,174	179,062
Accumulated deficit	(681,818)	(614,647)
Accumulated other comprehensive loss	(4,606)	(4,600)
Total stockholders' equity (deficit)	752	(440,184)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 455,316	$ 305,050

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(Unaudited)			
Revenue:				
Collaboration and license revenue	$ —	$ 6,551	$ 39,111	$ 17,738
Grant revenue	387	—	561	—
Total revenue	387	6,551	39,672	17,738
Operating expenses:				
Research and development	11,400	13,002	33,799	49,408
General and administrative	6,562	6,614	23,039	18,414
Total operating expenses	17,962	19,616	56,838	67,822
Operating loss	(17,575)	(13,065)	(17,166)	(50,084)
Investment income	2,573	1,299	4,932	4,024
Foreign currency transaction, net	—	(3)	—	39
Interest expense	—	(1,273)	—	(2,833)
Change in fair value of warrant liabilities	5,669	3,787	2,803	6,049
Change in fair value of contingent value right liability	(15,100)	—	(51,900)	—
Change in fair value of forward contract liabilities	—	—	(6,890)	—
Other income, net	250	253	1,050	753
Net loss	$ (24,183)	$ (9,002)	$ (67,171)	$ (42,052)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(15)	(20)	(6)	(69)
Unrealized gain on marketable securities	—	—	—	11
Total comprehensive income (loss)	$ (24,198)	$ (9,022)	$ (67,177)	$ (42,110)
Net loss per share:				
Basic and diluted	$ (1.13)	$ (1.74)	$ (4.61)	$ (8.20)

Weighted-average common shares outstanding:				
Basic and diluted	21,471,408	5,160,150	14,561,613	5,129,030

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Source: Cartesian Therapeutics, Inc.