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

August 8, 2024

Presented positive topline results from Phase 2b trial of Descartes-08 in patients with myasthenia gravis; End-of-Phase 2 meeting with FDA expected by year-end

Dosed first SLE patient in Phase 2 trial of Descartes-08

IND filing for pediatric basket study of Descartes-08 with focus in neurology and rheumatology expected by year-end

PIPE financing strengthened balance sheet, with net proceeds expected to support development of Descartes-08 in MG through planned Phase 3 trial

GAITHERSBURG, Md., Aug. 08, 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 second quarter of 2024, and provided recent business and corporate updates.

"Last quarter marked a pivotal milestone in Cartesian's history as we demonstrated clinical differentiation of our novel mRNA platform," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "MG patients treated with Descartes-08 were observed to have deep and durable responses, supporting the potential breadth and application of Cartesian's approach to treating autoimmune diseases. Additionally, we raised approximately $130 million from both new and existing investors to help us execute the planned Phase 3 trial of Descartes-08 in MG. We look forward to continuing our strong momentum, meeting with the FDA before year-end and initiating a Phase 3 clinical trial in MG, filing an IND for a pediatric basket study, and expanding our pipeline to address new disease indications."

Recent Pipeline Progress and Anticipated Milestones

Descartes-08 for Myasthenia Gravis (MG)

- In July 2024, the Company presented positive topline results from its Phase 2b trial of Descartes-08 in patients with generalized MG.
  - The trial achieved its primary endpoint with statistical significance in the pre-specified modified intent-to-treat efficacy population, with 71% (10/14) of patients treated with Descartes-08 observed to have 5-point or greater improvements in MG Composite (MGC) score at Month 3 compared to 25% (3/12) of patients treated with placebo (p=0.018).
  - Responders that reached their four-month and six-month assessments were observed to have deep, durable, and clinically meaningful improvements in their MGC severity scores.
  - Descartes-08 was observed to have a favorable safety profile supporting outpatient administration without the need for lymphodepleting chemotherapy.
- The Company expects to hold an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) by year-end 2024 to review data from the Phase 2b trial and discuss plans for initiating a Phase 3 clinical trial of Descartes-08 in MG. Descartes-08 was previously granted Regenerative Medicine Advanced Therapy (RMAT) Designation, which allows for more frequent regulatory engagement, and Orphan Drug Designation by the FDA for the treatment of MG.
- Descartes-08, the Company's lead product candidate, is an autologous anti-B cell maturation antigen (BCMA) mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA CAR-T).

Descartes-08 for Systemic Lupus Erythematosus (SLE)

- In July 2024, the Company announced dosing of the first patient in a Phase 2 clinical trial.
- The trial is designed to assess the safety, tolerability and clinical activity of outpatient Descartes-08 administration without preconditioning chemotherapy in patients with SLE.
- The Company believes that the mechanism of action of Descartes-08, which targets both

plasma cells and plasmacytoid dendritic cells, could lead to clinical benefit 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 for Pediatric Autoimmune Diseases

- Cartesian plans to file an Investigational New Drug (IND) application for Descartes-08 in pediatric autoimmune disease indications by year-end 2024.
- The planned basket trial will focus on certain pediatric neurological and rheumatological autoimmune diseases that have high unmet medical need.
- To date, Descartes-08 has been observed to have a favorable safety profile in adult patients treated in an outpatient setting without lymphodepleting chemotherapy, which the Company believes could be a key differentiator for treating pediatric patients.

Descartes-15 for Autoimmune Diseases

- The Company expects to dose the first patient in its planned Phase 1 trial of Descartes-15 in the second half of 2024.
- The Phase 1 dose escalation trial will 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.
- Descartes-15 is a next-generation autologous anti-BCMA mRNA CAR-T product candidate designed to have predictable and controllable pharmacokinetics, including technological advances that enhance CAR stability even in the presence of target-driven suppression of CAR.
- Similar to Descartes-08, Descartes-15 is designed to be administered without preconditioning chemotherapy and eliminate integrating vectors.
- Relative to Descartes-08, Descartes-15 has been observed to achieve an approximately ten-fold increase in CAR expression and selective target-specific killing in preclinical studies.

Corporate Updates

Completed $130 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.
- The Company intends to use the net proceeds from the PIPE financing, together with the Company's existing cash, cash equivalents, and restricted cash, to continue development of Descartes-08 in MG, specifically supporting anticipated manufacturing costs associated with a Phase 3 clinical trial and early commercial activities in preparation for a potential launch, if approved.
- Additionally, Cartesian expects to use the net proceeds to advance and expand its autoimmune pipeline through continued development of Descartes-08 for SLE, Descartes-15 for autoimmune diseases, and prepare for a planned basket trial for autoimmune pediatric indications.
- Operationally, the Company expects to continue making enhancements to its process development and manufacturing capabilities to improve production yields.

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. He has over 30 years of global development, regulatory, and commercial experience at leading pharmaceutical organizations.

Second Quarter 2024 Financial Results

- Cash, cash equivalents, and restricted cash were approximately $88.9 million as of June 30, 2024. In conjunction with net proceeds from the $130.0 million PIPE financing announced in July 2024, the Company's cash, cash equivalents, and restricted cash as of June 30, 2024 are expected to support development of Descartes-08 in MG, specifically supporting anticipated manufacturing costs associated with a Phase 3 clinical trial and early commercial activities in preparation for a potential launch, and help support the advancement and expansion of its autoimmune pipeline, including Descartes-08 for SLE, other potential indications, and enhancements to its process development and manufacturing capabilities.
- Research and development expenses were $12.7 million for the quarter ended June 30, 2024, compared to $17.8 million for the quarter ended June 30, 2023. The decrease in research and development expenses of $5.1 million for the quarter ended June 30, 2024 was due to a one-time cash charge to salaries and benefits as a result of headcount reduction in April 2023 and decreased contract license and milestone payments.
- General and administrative expenses were $7.0 million for the quarter ended June 30, 2024, compared to $6.1 million for the quarter ended June 30, 2023. The increase in general and administrative expenses of $0.9 million for the quarter ended June 30, 2024 was primarily due to personnel expenses.
- Net income was $13.8 million, or basic net income per share allocable to common stockholders of $0.58, for the quarter ended June 30, 2024, compared to net loss of $(11.4) million, or basic net loss per share allocable to common stockholders of $(2.23), for the quarter ended June 30, 2023. The net income includes recognition of revenue for a $30.0 million milestone fee, which was triggered by the initiation of a Biologics License Applications filing for SEL-212 by Swedish Orphan Biovitrum AB (Sobi). The milestone payment is expected to be paid out to Contingent Value Rights (CVR) holders in March 2025 net of deductions specified in the CVR Agreement.

About Descartes-08

Descartes-08, Cartesian's lead mRNA cell therapy candidate and a potential first-in-class mRNA-engineered chimeric antigen receptor T-cell therapy (mRNA CAR-T), is an autologous 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 does 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.

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 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 hold an End-of-Phase 2 meeting with the FDA by the end of 2024, the ability of Descartes-08 to be administered in an outpatient setting or without the need for preconditioning lymphodepleting chemotherapy, the Company's in-house manufacturing capabilities, 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, 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)

	June 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 87,227	$ 76,911
Accounts receivable	32,039	5,870
Unbilled receivables	3,472	2,981
Prepaid expenses and other current assets	2,044	4,967
Total current assets	124,782	90,729
Non-current assets:		
Property and equipment, net	6,672	2,113
Right-of-use asset, net	13,852	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	$ 347,738	$ 305,050
Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,862	$ 3,150
Accrued expenses and other current liabilities	10,954	15,572
Lease liability	2,523	2,166
Deferred revenue	—	2,311
Warrant liabilities	1,205	720
Contingent value right liability	8,571	15,983
Forward contract liabilities	—	28,307
Total current liabilities	26,115	68,209
Non-current liabilities:		
Lease liability, net of current portion	12,344	8,789
Deferred revenue, net of current portion	—	3,538
Warrant liabilities, net of current portion	8,055	5,674
Contingent value right liability, net of current portion	386,829	342,617
Deferred tax liabilities, net	15,853	15,853
Total liabilities	449,196	444,680
Series A Preferred Stock, $0.0001 par value; no and 548,375 shares authorized as of June 30, 2024 and December 31, 2023, respectively; no and 435,120.513 shares issued and outstanding as of June 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 June 30, 2024 and December 31, 2023, respectively; 166,341.592 and no shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Preferred stock, $0.0001 par value; 9,819,544.247 and 9,451,625 shares authorized as of June 30, 2024 and December 31, 2023, respectively; no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—

Common stock, $0.0001 par value; 350,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 17,816,238 and 5,397,597 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	2	1
Additional paid-in capital	560,766	179,062
Accumulated deficit	(657,635)	(614,647)
Accumulated other comprehensive loss	(4,591)	(4,600)
Total stockholders' deficit	(101,458)	(440,184)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 347,738	$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(Unaudited)			
Revenue:				
Collaboration and license revenue	$ 33,271	$ 5,249	$ 39,111	$ 11,187
Grant revenue	174	—	174	—
Total revenue	33,445	5,249	39,285	11,187
Operating expenses:				
Research and development	12,661	17,782	22,399	36,406
General and administrative	7,027	6,105	16,477	11,800
Total operating expenses	19,688	23,887	38,876	48,206
Operating income (loss)	13,757	(18,638)	409	(37,019)
Investment income	1,195	1,394	2,359	2,725
Foreign currency transaction, net	—	23	—	42
Interest expense	—	(752)	—	(1,560)
Change in fair value of warrant liabilities	(3,908)	6,341	(2,866)	2,262
Change in fair value of contingent value right liability	2,500	—	(36,800)	—
Change in fair value of forward contract liabilities	—	—	(6,890)	—
Other income, net	292	245	800	500
Net income (loss)	$ 13,836	$ (11,387)	$ (42,988)	$ (33,050)
Other comprehensive income (loss):				
Foreign currency translation adjustment	14	(27)	9	(49)
Unrealized gain on marketable securities	—	—	—	11
Total comprehensive income (loss)	$ 13,850	$ (11,414)	$ (42,979)	$ (33,088)
Net income (loss) per share allocable to common stockholders:				
Basic	$ 0.58	$ (2.23)	$ (3.88)	$ (6.46)
Diluted	$ 0.54	$ (2.23)	$ (3.88)	$ (6.46)
Weighted-average common shares outstanding:				
Basic	16,723,479	5,114,747	11,068,749	5,113,213
Diluted	17,791,143	5,114,747	11,068,749	5,113,213

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Cartesian THERAPEUTICS

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