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

May 8, 2024

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

On track to dose first patient in Phase 2 trial of Descartes-08 in SLE in 2Q24, as well as Phase 2 basket studies in additional autoimmune indications in 2H24

New headquarters expected to support scale of wholly owned, in-house cGMP manufacturing capabilities for clinical and commercial supply of Company's pipeline of mRNA cell therapy product candidates

Approximately $104.8M of cash, cash equivalents, and restricted cash as of March 31, 2024, expected to support planned operations into 2H 2026

GAITHERSBURG, Md., May 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 first quarter ended March 31, 2024, and recent corporate updates.

"We continue to make meaningful progress advancing our innovative pipeline of product candidates and remain on track to report topline results from the Phase 2b trial of our lead product candidate, Descartes-08 for MG, in mid-2024," said Carsten Brunn, Ph.D., President and Chief Executive Officer of Cartesian. "Looking ahead, we also expect to commence dosing in our Phase 2 trial of Descartes-08 in patients with SLE by the end of the second quarter. Descartes-08 is designed with our novel mRNA-engineered CAR-T technology, is not expected to require preconditioning chemotherapy, and is intended to be administered in an outpatient setting. We remain confident Descartes-08 has the potential to expand the reach of cell therapy to patients with autoimmune diseases and serve as the first CAR-T cell therapy for the treatment of autoimmunity."

Dr. Brunn continued, "Additionally, we were excited to announce plans to transition to new corporate headquarters in Frederick, Maryland, that will provide us with the infrastructure to support our next phase of growth. We expect this new facility will allow us to scale our wholly owned, in-house cGMP manufacturing capabilities for late-stage clinical and commercial supply of our mRNA cell therapy product candidates, while continuing to maintain control over product quality and production."

Recent Pipeline Progress and Anticipated Milestones

Descartes-08 for Myasthenia Gravis (MG)

- Topline data from randomized Phase 2b trial in patients with MG on track for mid-2024.
- Recently granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of MG.
- Previously disclosed positive, long-term follow-up results from Phase 2a trial. In April 2024, the Company announced that these data will be featured in an oral presentation at the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting on May 10, 2024 in Baltimore, Maryland.
- 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)

- Dosing of first patient in Phase 2 trial of Descartes-08 in patients with SLE expected in second quarter of 2024.
- The Phase 2 trial 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 and impacts approximately 1.5 million people in the United States.

Descartes-15 for Multiple Myeloma

- Planning for the first-in-human Phase 1 dose escalation trial is underway to assess the safety and tolerability of outpatient Descartes-15 administration in patients with multiple myeloma.
- Descartes-15 is a next-generation autologous anti-BCMA mRNA CAR-T product candidate designed to have predictable and controllable pharmacokinetics, potentially circumventing preconditioning chemotherapy, and avoiding the risk of genomic integration.
- The Company expects to subsequently assess Descartes-15 in autoimmune indications.

Corporate Updates

Preferred Stock Conversion and Reverse Stock Split Approved at Special Meeting of Stockholders

- In March 2024, Cartesian announced the approval for the conversion of the Company's Series A Non-Voting Convertible Preferred Stock into the Company's common stock and a 1-for-30 reverse stock split of the Company's common stock.
- Following the reverse stock split and the automatic conversion of the Company's Series A Non-Voting Convertible Preferred Stock into common stock, the number of issued and outstanding shares of the Company's common stock is approximately 17.8 million shares.

Transitioning Corporate Headquarters to Frederick, Maryland

- In March 2024, the Company announced plans to transition its corporate headquarters to Frederick, Maryland. Following this announcement, Cartesian further expanded the footprint of this facility by approximately 30% through an amended agreement.
- The Company now has approximately 27,000 square feet of state-of-the-art current good manufacturing practice (cGMP) compliant manufacturing and laboratory space, as well as general and administrative office space to support the Company's continued growth. This facility reinforces the development of Cartesian's clinical and preclinical programs through clinical and commercial manufacturing scale capabilities and advanced research and development laboratory space.
- By conducting all manufacturing in-house, Cartesian expects to optimize processes more rapidly and iteratively while directly working to ensure adherence to strict quality standards. The Company believes this facility will facilitate production of potent yet safer, cost-effective mRNA cell therapy product candidates for late-stage clinical and commercial supply.

First Quarter 2024 Financial Results

- Cash, cash equivalents, and restricted cash of approximately $104.8 million as of March 31, 2024. The Company's cash, cash equivalents and restricted cash as of March 31, 2024 is expected to support planned operations and the development of Cartesian's pipeline into the second half of 2026, including the planned Phase 3 trial of Descartes-08 in MG.
- Research and development expenses were $9.7 million for the quarter ended March 31, 2024, compared to $18.6 million for the quarter ended March 31, 2023. The decrease in research and development expenses of $8.9 million for the quarter ended March 31, 2024 was primarily the result of reductions in expenses incurred for preclinical and clinical programs due to the strategic reprioritization in the Company's clinical pipeline.

- General and administrative expenses were $9.5 million for the quarter ended March 31, 2024, compared to $5.7 million for the quarter ended March 31, 2023. The increase in expense of $3.8 million for the quarter ended March 31, 2024 was primarily due to an increase in professional fees incurred in connection with the Company's merger in November 2023.

- Net loss was $(56.8) million, or $(10.50) per share (basic/diluted), for the quarter ended March 31, 2024, compared to net loss of $(21.7) million, or $(4.24) per share (basic/diluted), for the quarter ended March 31, 2023.

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 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 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 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 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)

	March 31, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 103,418	$ 76,911
Accounts receivable	2,006	5,870
Unbilled receivables	2,370	2,981
Prepaid expenses and other current assets	3,315	4,967
Total current assets	111,109	90,729
Non-current assets:		
Property and equipment, net	2,402	2,113
Right-of-use asset, net	9,556	10,068
In-process research and development assets	150,600	150,600
Goodwill	48,163	48,163
Long-term restricted cash	1,377	1,377
Investments	2,000	2,000
Total assets	$ 325,207	$ 305,050

Liabilities, convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,517	$ 3,150
Accrued expenses and other current liabilities	9,516	15,572
Lease liability	2,229	2,166
Deferred revenue	412	2,311
Warrant liabilities	597	720
Contingent value right liability	21,383	15,983
Forward contract liabilities	—	28,307
Total current liabilities	36,654	68,209
Non-current liabilities:		
Lease liability, net of current portion	8,228	8,789
Deferred revenue, net of current portion	—	3,538
Warrant liabilities, net of current portion	4,755	5,674
Contingent value right liability, net of current portion	376,517	342,617
Deferred tax liabilities, net	15,853	15,853
Total liabilities	442,007	444,680
Series A Preferred Stock, $0.0001 par value; no and 548,375 shares authorized as of March 31, 2024 and December 31, 2023, respectively; no and 435,120.513 shares issued and outstanding as of March 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; 548,375 and no shares authorized as of March 31, 2024 and December 31, 2023, respectively; 534,260.839 and no shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Preferred stock, $0.0001 par value; 9,451,625 shares authorized as of March 31, 2024 and December 31, 2023, respectively; no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 5,515,836 and 5,397,597 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	559,275	179,062
Accumulated deficit	(671,471)	(614,647)
Accumulated other comprehensive loss	(4,605)	(4,600)
Total stockholders' deficit	(116,800)	(440,184)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 325,207	$ 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 March 31,	
	2024	**2023**
	(Unaudited)	
Collaboration and license revenue	$ 5,840	$ 5,938
Operating expenses:		
Research and development	9,738	18,624
General and administrative	9,450	5,695
Total operating expenses	19,188	24,319
Operating loss	(13,348)	(18,381)
Investment income	1,164	1,331
Foreign currency transaction, net	—	19
Interest expense	—	(808)
Change in fair value of warrant liabilities	1,042	(4,079)
Change in fair value of contingent value right liability	(39,300)	—
Change in fair value of forward contract liabilities	(6,890)	—
Other income, net	508	255
Net loss	$ (56,824)	$ (21,663)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	(5)	(22)
Unrealized gain (loss) on marketable securities	—	11
Total comprehensive loss	$ (56,829)	$ (21,674)

Net loss per share:

Basic and Diluted	$ (10.50)	$ (4.24)
Weighted-average common shares outstanding:		
Basic and Diluted	5,414,020	5,111,518

Investor Contact

Ron Moldaver
ron.moldaver@cartesiantx.com

Media Contact
David Rosen
Argot Partners
cartesian@argotpartners.com

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