

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 8, 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 August 8, 2024, Cartesian Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2024. 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.

Item 7.01. Regulation FD Disclosure.

The Company from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. A copy of its current corporate slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.2.

The information in Items 2.02 and 7.01 of this Form 8-K, including Exhibits 99.1 and 99.2 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. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Exhibit Description</u>
99.1	Press Release of Cartesian Therapeutics, Inc. dated August 8, 2024
99.2	Corporate slide presentation of Cartesian Therapeutics, Inc. dated August 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: August 8, 2024

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

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

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, August 8, 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 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 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 (Unaudited)	December 31, 2023
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

Investor Contact

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CARTESIAN THERAPEUTICS

Pioneering mRNA Cell Therapy for Autoimmunity

August 2024



Forward-Looking Statements

Disclosures

For the purposes of this notice, the "presentation" that follows shall mean and include the slides that follow, the oral presentation of the slides by members of management of Cartesian Therapeutics, Inc. (the "Company") or any person on their behalf, any question-and-answer session that follows such oral presentation, hard copies of this document and any materials distributed at, or in connection with, such oral presentation.

Forward-looking Statements

Any statements in this presentation 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 pro forma cash resources, conversion of the Company's Series B Non-Voting Convertible Preferred Stock and remaining Series A Non-Voting Convertible Preferred Stock, 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, Descartes-33 and the Company's other product candidates to treat myasthenia gravis, systemic lupus erythematosus, or any other disease, 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 Army® 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 presentation 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 presentation, except as required by law.

Clinical-stage company pioneering mRNA cell therapies designed to expand the reach of cell therapy to autoimmunity

- Pipeline of mRNA cell therapies designed to be dosed more reliably and safely in an outpatient setting **without lymphodepletion**
- Descartes-08: Potential first-in-class mRNA CAR T-cell (CAR-T) with **deep and durable responses** observed in randomized, double-blind, placebo-controlled Phase 2b trial in patients with myasthenia gravis (MG)
- **Wholly-owned GMP manufacturing** designed to enable rapid optimization of processes in iterative manner

Cartesian
BIOLOGICS

MULTIPLE ANTICIPATED NEAR-TERM CATALYSTS

DESCARTES-08

- EoP2 meeting with FDA to discuss MG Phase 3 plan expected by end of 2024
- Initiation of Phase 2 autoimmune basket trial expected in 2H 2024

DESCARTES-15

- Next-generation mRNA CAR-T candidate
- Dosing of first patient expected by year-end in first-in-human Phase 1 clinical trial

PRO FORMA CASH RESOURCES

Strong balance sheet with approximately \$213.3 million*

Expected to support continued clinical development of Descartes-08 in MG through Phase 3 and early commercial activities, as well as continued development and expansion of autoimmune pipeline

* Includes approximately \$68.9 million of cash, cash equivalents, and restricted cash as of June 30, 2024, and net proceeds from PIPE financing in July 2024.
GMP: Good manufacturing practices

CAR, Chimeric antigen receptor
SLE, Systemic Lupus Erythematosus
EoP2, End of Phase 2
FDA, Food and Drug Administration

Experienced management team to lead the mRNA cell therapy company of the future

MANAGEMENT



Carsten Brunn, PhD
President and CEO



Blaine Davis
CFO



Metin Kurtoglu, MD, PhD
CTO



Emily English, PhD
SVP, Head of Manufacturing Operations



Chris Jewell, PhD
CSO



Milos Mijlkovic, MD
CMO



Jessica Keliher
CPO



Matthew Bartholomae
General Counsel

BOARD MEMBERS



Carrie S. Cox
Chairman



Timothy Barabe
Director



Nishan De Silva, MD
Director



Murat Kalayoglu, MD, PhD
Director



Kemal Malik, MBBS
Director



Michael Singer, MD, PhD
Director








Timothy Springer, PhD
Director



Patrick Zenner
Director

Cartesian's mRNA approach is designed to expand the reach of potent cell therapy products to address autoimmunity

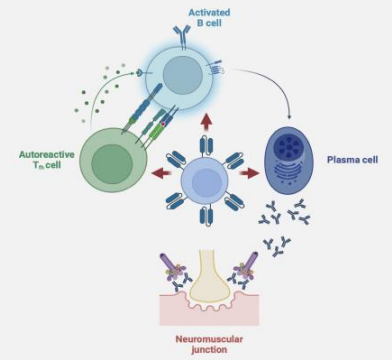
No Lymphodepletion		<ul style="list-style-type: none">• mRNA cell therapy does not require lymphodepleting chemotherapy• No associated cytopenia, secondary malignancies, or other chemotherapy toxicities
Administered Outpatient		<ul style="list-style-type: none">• Reduced burden on patients, caregivers, and healthcare system• Convenient dosing schedule
Transient Cell Modification		<ul style="list-style-type: none">• mRNA does not replicate and allows for more predictable response• Does not carry risk of genomic integration
Delivered at Therapeutic Levels		<ul style="list-style-type: none">• Administered at therapeutic doses without uncontrollable proliferation• Transient CAR protein expression due to mRNA degradation and natural dilution
In-House cGMP Manufacturing		<ul style="list-style-type: none">• Control over product quality and production• Autologous approach with approximately three weeks from apheresis to first infusion

Descartes-08 is believed to be the first mRNA CAR-T in clinical development for autoimmune disease

Engineered by transfection of autologous CD8+ T cells with mRNA encoding anti-BCMA CAR

Typical lot processed for infusion within ~3 weeks

Granted U.S. FDA orphan and RMAT designations for generalized myasthenia gravis



Myasthenia gravis is a rare, progressive autoimmune disease with significant unmet need

The infographic is divided into three main sections. The top-left section, on a light blue background with a grid of human icons, displays the text '>120,000 Patients in the U.S. and EU' in large, bold font, with a smaller box below it stating 'Significant unmet need remains'. The top-right section, on a dark blue background, is titled 'Characterized by debilitating fatigue and muscle weakness' and features four icons representing affected areas: 'Limbs' (a stick figure), 'Respiratory' (lungs), 'Ocular' (an eye), and 'Facial' (a head profile). The bottom section, also on a dark blue background, contains the text 'Current treatments require chronic or frequent administration and have limited durability' flanked by icons of a pill bottle and an IV drip.

Descartes-08 in MG

Phase 2b Topline Results

- Responders observed to have ~3x greater improvements than clinically meaningful*
- Deep, durable responses and favorable safety profile observed in highly symptomatic, heavily pre-treated patients with MG
- Novel design: randomized double-blind placebo-controlled trial of engineered cell therapy in autoimmunity

Cartesian



Met primary endpoint

- 71% response rate at Month 3 for Descartes-08 patients vs. 25% for placebo (p<0.05)



Deep, durable responses observed in patients treated with Descartes-08



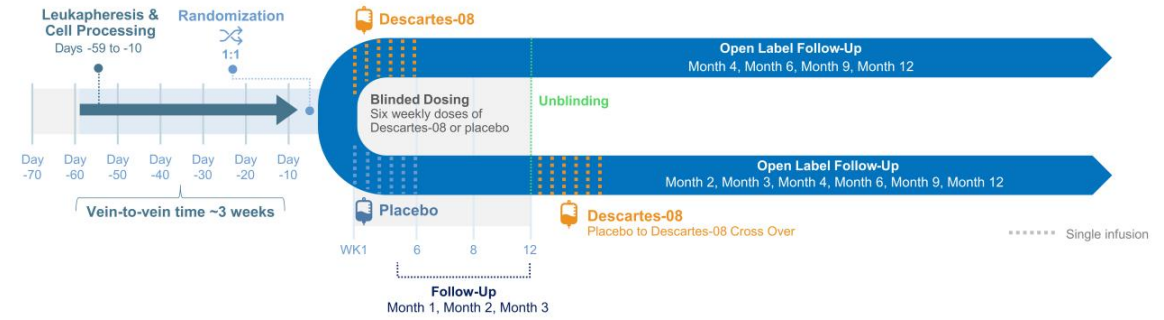
Safety profile continues to support outpatient administration



Data support advancement to Phase 3

*Clinically meaningful response: three-point reduction in MG Composite score from baseline

Phase 2b trial: double-blind, placebo-controlled clinical trial of Descartes-08 in patients with myasthenia gravis



INCLUSION CRITERIA

- Non-MuSK-MG
- MGFA Class II-IV
- MG-ADL ≥ 6
- Severe disease despite stable doses of immunosuppressants

PRIMARY ENDPOINT

- Proportion of patients with MG Composite improvement of ≥ 5 -points at Month 3, relative to placebo
- Predefined primary efficacy dataset

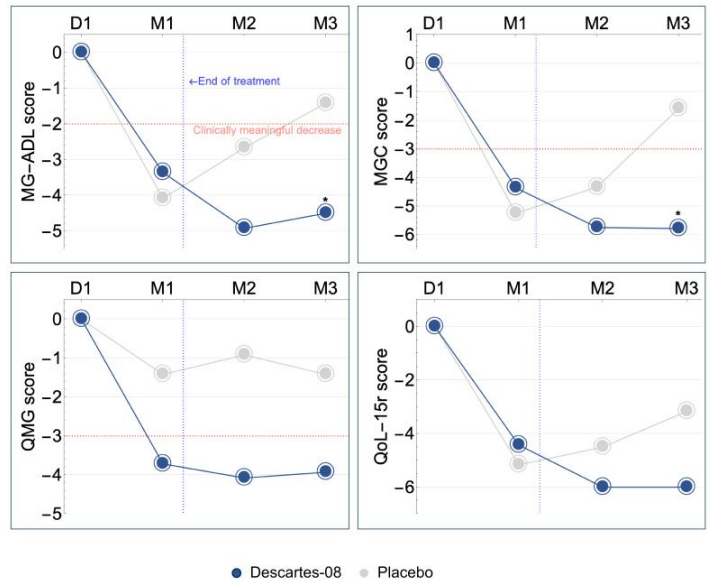
SECONDARY OBJECTIVES

- Safety and tolerability from predefined safety dataset
- Quantify clinical effect of Descartes-08 over 1 year
- QMG, MG QoL 15R, MG-ADL (change from baseline to Month 3)
- Compare effect of Descartes-08 versus placebo on MG scales (change from baseline to Month 3) in patients who cross over from placebo to Descartes-08

Statistically significant improvements observed in Descartes-08 patients at Month 3 assessment

- Non-responders (n=4)
 - 1 LRP4+ MG non-responder at Month 3 onward
 - 1 additional non-responder at Month 3 onward
 - 1 responded during open label follow-up
 - 1 has not reached 1st open label follow-up
- Placebo response generally in line with expectations

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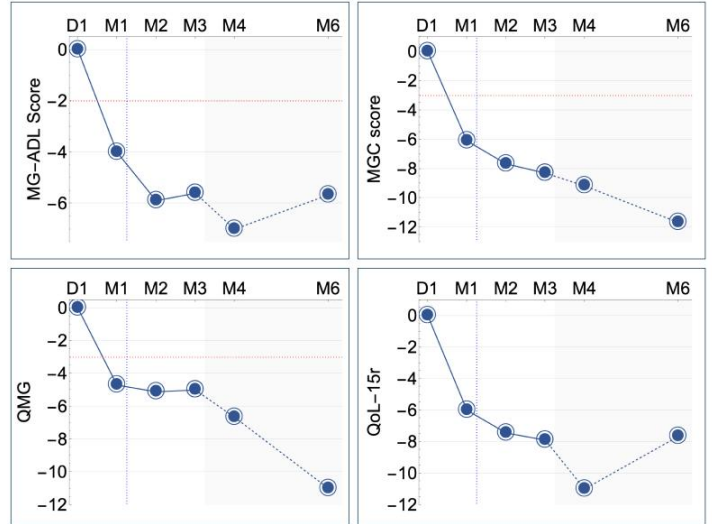


Mean decrease from Baseline in the prespecified primary efficacy population (n=26)
 * p<0.05 by Mann-Whitney U test at Month 3 in MGC and MG-ADL
 LRP4+, low-density lipoprotein receptor-related protein 4

Deep and durable responses observed in Descartes-08 responders through Month 6

- Results consistent with Phase 2a open-label trial findings

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Mean decrease from Baseline in MGC Responders (participants who achieved a ≥ 5 -point reduction in MGC at Month 3, n=10. Month 4 n=5, Month 6 n=3).

Observed safety results support outpatient administration and in line with Phase 2a observations

- No cytokine release syndrome
- No neurotoxicity or ICANS
- Most AEs were transient or mild

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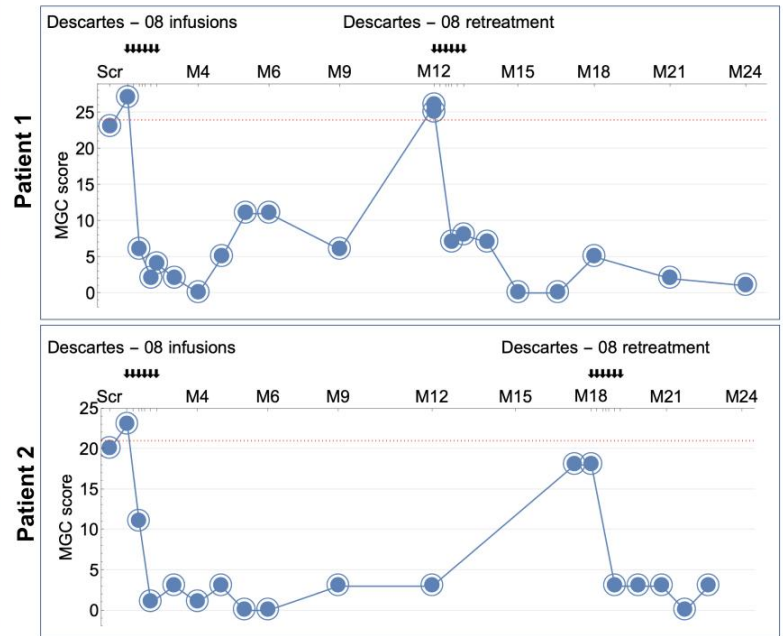
	Descartes-08 (n=19)			Placebo (n=17)		
	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
Headache	6 (32%)	4 (21%)		2 (12%)	3 (18%)	
Chills	7 (37%)	4 (21%)		1 (6%)		
Nausea	2 (11%)	5 (26%)		2 (12%)	2 (12%)	
Fever	6 (32%)	3 (17%)	1 (6%)			
Fatigue	5 (26%)	1 (5%)		1 (6%)		
Myalgia	3 (16%)	3 (16%)		1 (6%)		
Infusion related reaction	1 (5%)	2 (11%)	1 (6%)	1 (6%)		
Muscle weakness	1 (5%)	1 (5%)		1 (6%)		
Arthralgia		1 (5%)		1 (6%)	1 (6%)	
Tachycardia	3 (16%)					
Herpes simplex reactivation	2 (11%)		1 (6%)			
Dysgeusia	3 (16%)					
Diarrhea	1 (5%)				1 (6%)	
Sweating	1 (5%)			1 (6%)		
Limb edema	1 (5%)	1 (5%)				
Flushing	2 (11%)					
Dyspnea	1 (5%)	1 (5%)				
Insomnia	2 (11%)					
Vomiting	2 (11%)					
Tremor	2 (11%)					

Safety dataset comprises all subjects who received at least one dose of Descartes-08 (n=19) or placebo (n=17). All Grade 1–2 adverse events deemed possibly, probably or definitely related to the study drug with a cumulative incidence $\geq 10\%$ and all Grade 3 adverse events deemed possibly, probably or definitely related to the study drug are reported. There were no Grade 4 adverse events.
AE, Adverse event

Phase 2a update: Descartes-08 retreatment led to sustained clinically meaningful responses

- Retreated patients experienced rapid improvement in clinical scores and maintained minimal symptom expression for up to one year after receiving second treatment cycle

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Manuscript submitted for peer review; pre-print available at medRxiv.org

Planned next steps for Descartes-08 in MG

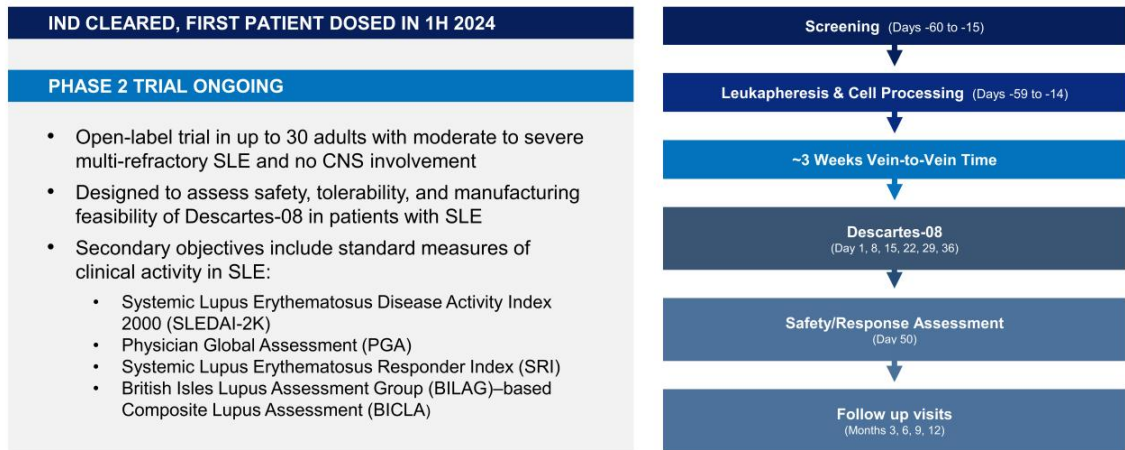
EoP2 meeting with FDA
expected **by year-end**



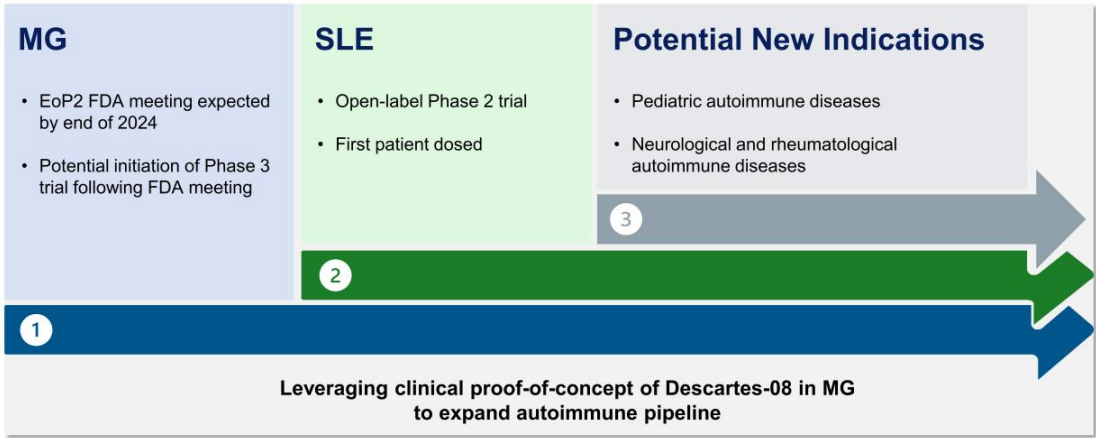
Initiate Phase 3
clinical trial

**RMAT designation to support efficient development
plan in collaboration with FDA**

Exploring potential of Descartes-08 in Systemic Lupus Erythematosus (SLE)



Intend to leverage the potential of Descartes-08 across multiple clinical programs

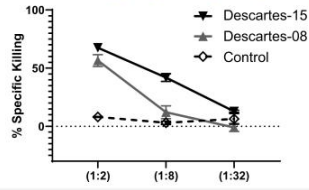


Descartes-15, a next generation anti-BCMA mRNA CAR-T with >10x potency observed in preclinical studies

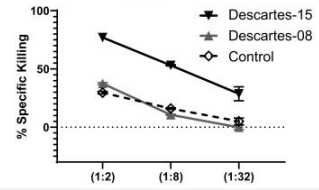
Descartes-15 is an anti-BCMA mRNA CAR-T with potential disruptive features:

- Engineered for maximum potency and CAR stability, even in the presence of target-driven suppression of CAR
- Clinical strategy expected to leverage safety and clinical activity data from Descartes-08

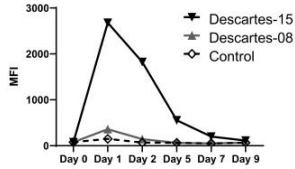
Potent killing (single target exposure)



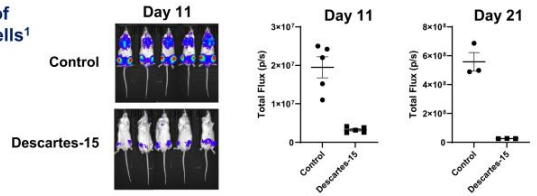
Persistent killing (multiple exposures)



Superior CAR expression



Efficient killing of BCMA+ target cells¹



Wholly-owned, in-house manufacturing: 27,000 sq. ft. state-of-the-art cGMP facility



Clinical and commercial manufacturing scale capabilities support maturing pipeline and future growth



Flexibility to quickly adapt to changes in processes or needs



Ownership of quality control and production timelines



Potential cost efficiency

Facility located in Frederick, MD

Maturing pipeline offers potential for multiple catalysts

Descartes-08 in MG

EoP2 meeting with FDA expected by **end of 2024**;
potential initiation of Phase 3 trial to follow

Descartes-08 in SLE

Phase 2 open-label trial ongoing, with first patient
dosed in **1H 2024**

Descartes-08 Pediatric Basket Trial

Plan to file IND for Phase 2 pediatric basket trial in
neurological and rheumatological autoimmune
indications in **2H 2024**

Descartes-15

Phase 1 first-in-human trial underway with first patient
dosing expected in **2H 2024**

**Strong
Financial
Position
Expected to
Support
Pipeline
Through Key
Milestones**

Cartesian
CORPORATION

\$213.3M

Includes approximately \$88.9 million in cash, cash equivalents, and restricted cash as of June 30, 2024, and net proceeds from July 2024 PIPE financing

**<60 FULL TIME
EMPLOYEES**

Based in Gaithersburg, MD and Frederick, MD

21.4M 29.9M 33.3M

Basic shares outstanding
as of 8/7/24*

Basic shares outstanding upon
full conversion of outstanding
Series A and Series B Preferred**

Fully diluted shares
outstanding***

*Includes settlement of 3.6 million common stock from July 2024 PIPE financing.

**Further includes approximately 166.3 thousand shares of Series A Non-Voting Convertible Preferred Stock and approximately 2.9 million shares of Series B Non-Voting Convertible Preferred Stock that remain subject to beneficial ownership limitations that are convertible into approximately 5.5 million and 2.9 million shares of common stock, respectively. The conversion of the Series B Non-Voting Convertible Preferred Stock remains subject to stockholder approval.

***Further includes outstanding options, RSUs and warrants.

PIPE, Private investment in public equity

PIONEERING mRNA CELL THERAPIES

Pipeline designed to expand the reach of cell therapy to autoimmunity

MATURING PIPELINE WITH EXPECTED NEAR-TERM CATALYSTS

Clinically differentiated platform with EoP2 meeting for Descartes-08 in MG planned by year-end

EXPERIENCED LEADERSHIP TEAM

Focused on disciplined investment and creating value for stockholders and patients

STRONG BALANCE SHEET TO SUPPORT MATURING PIPELINE

Current pro forma cash expected to support Descartes-08 through Phase 3 and early commercial activities, expansion of autoimmune pipeline, and enhancements to manufacturing capabilities



Cartesian[®]
THERAPEUTICS

CARTESIAN THERAPEUTICS

Pioneering mRNA Cell Therapy for Autoimmunity



Appendix

Descartes-08 is designed for dual action, precisely targeting two key BCMA+ cell populations involved in a spectrum of autoimmune diseases

Descartes-08 is designed to target BCMA, a surface antigen expressed on **plasma cells/plasmablasts** and **plasmacytoid dendritic cells**

PLASMA CELLS (PCs) AND PLASMABLASTS

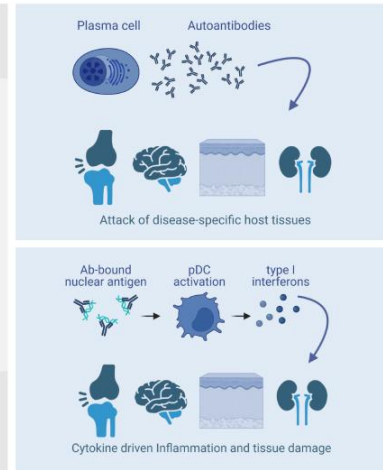
- PCs, plasmablasts and proliferating B cells targeted by Descartes-08 represent a tiny fraction of B cells
- These cells are entirely responsible for secreting pathogenic autoantibodies
- During autoimmunity, autoantibodies attack host tissue and drive inflammation

PLASMACYTOID DENDRITIC CELLS (pDCs)

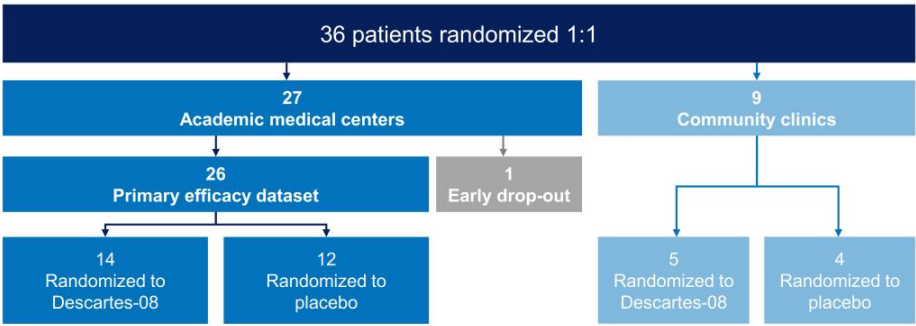
- pDCs, which Descartes-08 is designed to target, are a rare subset of antigen-presenting cells
- These cells secrete high levels of cytokines (i.e., type I interferons) that cause inflammation and tissue damage during many human autoimmune diseases
- pDCs are increased in patients with autoimmunity (e.g., SLE) and interfere with optimal treatment

Several autoimmune disease segments involve pathogenic contributions from **both PCs/plasmablasts** and **pDCs**, including rheumatology, nephrology, neurology, and others

Selectively deleting PCs/plasmablasts and pDCs, if successful, may create a differentiated cell therapy platform



Phase 2b: 14 patients received Descartes-08 and 12 patients received placebo in the pre-specified primary efficacy dataset



- Consistent with current IND, primary efficacy dataset includes modified ITT population enrolled at academic medical centers qualified for MG Composite assessment with at least one post-baseline follow-up.
- Safety dataset includes all participants at academic medical centers and community clinics who received at least one dose of Descartes-08 or placebo.

Phase 2b baseline characteristics: highly symptomatic patient population with severe disease

		Descartes-08	Placebo	Total
	Mean age, years (SD)	56.7 (16.7)	60 (13.4)	58.2 (15.0)
	Female	10 (71%)	6 (50%)	16 (62%)
	Male	4 (29%)	6 (50%)	10 (38%)
Weight	Mean weight, kg (SD)	94.1 (20.7)	104.0 (26.6)	98.7 (23.7)
Race and ethnicity	White, non-Hispanic	12 (86%)	12 (100%)	24 (92%)
	Other	2 (14%)	0 (0%)	2 (8%)
MGFA class at screening	II	4 (29%)	3 (25%)	7 (27%)
	III	9 (64%)	9 (75%)	18 (69%)
	IV	1 (7%)	0 (0%)	1 (4%)
	Median age of disease onset, years (range)	55 (16–76)	50 (25–71)	51 (16–76)
	Median duration of disease, years (range)	5 (2–23)	10 (4–26)	6 (2–26)
MG antibody status	Anti-AChR antibody	10 (71%)	9 (75%)	19 (73%)
	Anti-LRP4 antibody	1 (7%)	0 (0%)	1 (4%)
	Seronegative ¹	3 (21%)	3 (25%)	6 (23%)
	QMG	16.9 (7.2)	15.1 (4.0)	15.1 (4.0)
Mean baseline scores (SD)	MG-ADL	10.1 (2.9)	10.3 (3.2)	10.3 (3.2)
	MGC	16.1 (6.4)	16.1 (4.0)	16.1 (5.4)
	MG-QoL-15r	19.5 (7.7)	17.3 (4.7)	18.5 (6.5)

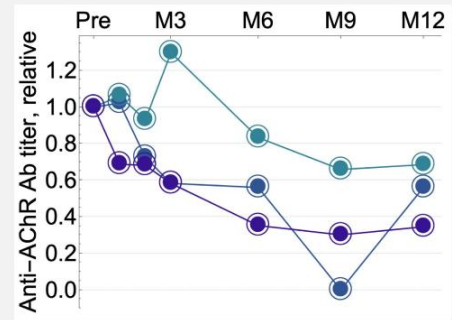
Phase 2b prior and ongoing treatments: heavily pre-treated patient population

		Descartes-08	Placebo	Total
Previous myasthenia gravis therapies (standard of care)	Pyridostigmine	9 (64%)	8 (67%)	17 (65%)
	Prednisone	8 (57%)	6 (50%)	14 (54%)
	Other immunosuppressants	8 (57%)	9 (75%)	17 (65%)
	Complement inhibitor	3 (21%)	5 (42%)	8 (31%)
	FcRN antagonist	4 (29%)	5 (42%)	9 (35%)
Previous intravenous immunoglobulin	Previous intravenous immunoglobulin	10 (71%)	10 (83%)	20 (77%)
	Previous plasma exchange	3 (21%)	6 (50%)	9 (35%)
	Diagnosis of thymoma*	0 (0%)	5 (42%)	5 (19%)
	Previous thymectomy	3 (21%)	7 (58%)	10 (38%)
	Previous MG crisis requiring intubation	2 (14%)	0 (0%)	2 (8%)
MG ongoing therapy	Pyridostigmine	9 (69%)	7 (58%)	16 (62%)
	Prednisone	8 (57%)	4 (33%)	12 (46%)
	Azathioprine	5 (21%)	1 (8%)	4 (15%)
	Mycophenolate mofetil	2 (14%)	5 (41%)	7 (27%)
	Complement inhibitor	1 (7%)	2 (14%)	3 (12%)

Descartes-08: Durable depletion of autoantibodies consistent with observed clinical responses and MoA

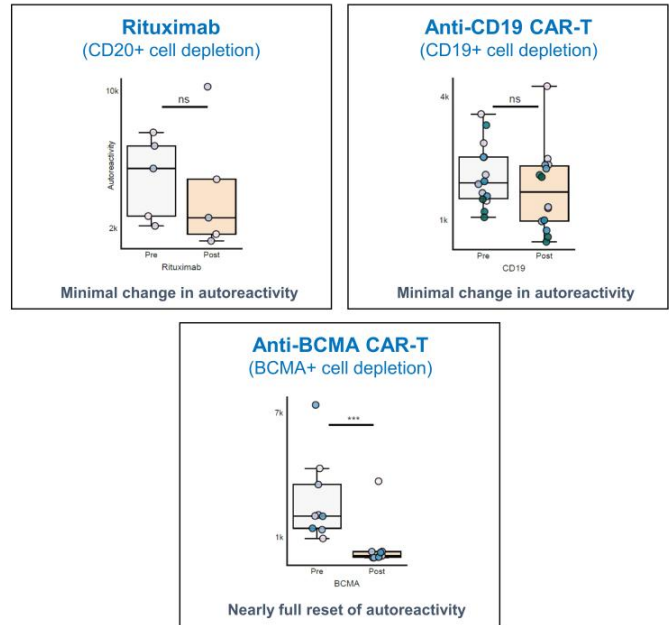
- Three participants from Phase 2a study with detectable AChR antibody levels at baseline experienced autoantibody reductions by Month 6
- Reductions deepened further by Month 9, and were maintained at Month 12

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Manuscript submitted for peer review; pre-print available at medRxiv.org
Anti-acetylcholine receptor, AChR MoA, Mechanism of action

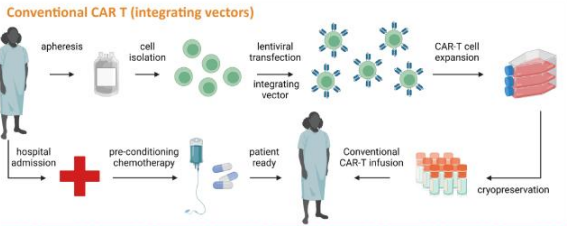
Clinical analyses of antigen-depletion therapies show BCMA-targeting with CAR-T may enable precision reset of autoantibody-producing PCs



Cartesian differentiation: Approved CAR-T therapies and other trials in the autoimmune space face fundamental hurdles created by integrating vectors

Conventional CAR-T (integrating viral vectors) targeting CD19

- Creates significant burden for patients in three areas
 - hospital admission
 - lymphodepletion/chemotherapy
 - cytokine release syndrome (CRS) risk
- Patients with autoimmunity typically have much lower tolerance for these hurdles relative to cancer patients



mRNA CAR T (no integration) targeting BCMA

- mRNA enables transient expression → no need for significant T cell proliferation
- Eliminates lymphodepletion and enables outpatient administration without CRS

