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

August 8, 2024
Date of Report (Date of earliest event reported)

CABALETTA BIO, INC.
(Exact name of Registrant as Specified in its Charter)

Delaware	**001-39103**	**82-1685768**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2929 Arch Street, Suite 600, Philadelphia, PA	**19104**
(Address of principal executive offices)	**(Zip Code)**

(267) 759-3100
(Registrant's telephone number, including area code)

Not Applicable
(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 $0.00001 per share	CABA	The Nasdaq Global Select Market

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, Cabaletta Bio, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2024. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for the 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 and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure

On August 8, 2024, the Company posted to the "Investors & Media" section of the Company's website at *www.cabalettabio.com* an updated corporate presentation (the "Corporate Presentation"). A copy of the Corporate Presentation is attached hereto as Exhibit 99.2 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by the registrant on August 8, 2024, furnished herewith.
99.2	Cabaletta Bio, Inc. Corporate Presentation, dated August 8, 2024, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CABALETTA BIO, INC.

Date: August 8, 2024

By: /s/ Steven Nichtberger
Steven Nichtberger, M.D.
President and Chief Executive Officer

Exhibit 99.1

Cabaletta Bio®

Cabaletta Bio Reports Second Quarter 2024 Financial Results and Provides Business Update

– Nine patients enrolled as of August 5, 2024 across the RESET™ clinical development program, including four since EULAR in June, with 22 U.S. clinical sites now enrolling –

– Additional clinical data from the RESET-Myositis™ and RESET-SLE™ trials as well as initial clinical data from the RESET-SSc™ and RESET-MG™ trials anticipated in 2H24 –

– Initial clinical and translational data from each of the first patients in the RESET-Myositis and RESET-SLE trials presented at EULAR in June 2024 –

– An LN patient with very active, refractory disease dosed with CABA-201 in late June experienced a protocol-defined dose-limiting toxicity of Grade 4 ICANS, which resolved rapidly following standard management; the independent data monitoring committee recommended the study to proceed as designed, without delay, at the current dose –

– Recently signed Lonza and Cellares agreements support progression into next stage of manufacturing strategy to support expansion of clinical supply while preparing to efficiently scale commercial supply for CABA-201 –

– Cash, cash equivalents and short-term investments total $203.2 million as of June 30, 2024, expected to support operations into the first half of 2026 –

PHILADELPHIA, Aug. 8, 2024 – Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases, today reported financial results for the second quarter ended June 30, 2024, and provided a business update.

"We have seen increased enrollment and additional clinical sites open since presenting positive initial clinical and translational data for the first two patients dosed with CABA-201 at the EULAR 2024 Congress in June. We look forward to sharing additional clinical data on CABA-201 in the second half of this year," said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. "In addition, we have recently advanced our manufacturing strategy for CABA-201 through a new CDMO agreement with Lonza and by expanding our existing fully automated manufacturing collaboration with Cellares. We have also added Sarah Yuan, Ph.D., as our Chief Technology Officer. Sarah brings substantial cell therapy development and commercial launch experience, including at bluebird bio and 2seventy bio, where she was instrumental in the regulatory approval process for Abecma™ and two other cell therapy medicines. With the momentum and milestones achieved in the second quarter and recent period, we believe we are well positioned to realize our vision of developing and launching the first curative targeted cell therapy for patients with autoimmune diseases."

Recent Operational Highlights and Upcoming Anticipated Milestones

Chimeric Antigen Receptor T cells for Autoimmunity (CARTA) Strategy

CABA-201: Autologous, engineered T cells designed with a chimeric antigen receptor containing a fully human CD19 binder and a4-1BB co-stimulatory domain as a potential treatment for a broad range of autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease.

Rheumatology Portfolio

- **Myositis (idiopathic inflammatory myopathies, IIM)**
    - In June 2024, Cabaletta reported positive initial clinical data on the first patient in the immune-mediated necrotizing myopathy (IMNM) cohort of the Phase 1/2 RESET-Myositis trial with three months of follow-up. The data were presented at a satellite symposium at the EULAR 2024 Congress.
    - Patient enrollment in the RESET-Myositis trial is ongoing and additional clinical data from the trial are expected in the second half of 2024.
- **Systemic lupus erythematosus (SLE)**
    - In June 2024, Cabaletta reported positive initial clinical data on the first patient in the SLEnon-renal cohort of the Phase 1/2 RESET-SLE trial with one month of follow-up. The data were presented at a satellite symposium at the EULAR 2024 Congress.
    - In late June 2024, a lupus nephritis (LN) patient with very active, refractory disease was dosed with CABA-201 and subsequently experienced a protocol-defined dose-limiting toxicity of grade 4 immune effector cell-associated neurotoxicity syndrome (ICANS). The ICANS resolved rapidly following standard management. After data review, the Independent Data Monitoring Committee recommended that the study proceed at the current dose without delay. The Company has proposed and is implementing protocol modifications designed to improve patient safety, including enhanced monitoring for fever and neurologic symptoms along with seizure prophylaxis for all patients, in line with the practice at many academic sites including at Erlangen University, the site of the CD19-CAR T studies led by Dr. Georg Schett. Last month, the Company communicated details of the event and proposed protocol changes to all active clinical sites within the RESET clinical trial program.
    - Patient enrollment in both cohorts of the RESET-SLE trial is ongoing and additional clinical data from the trial are expected in the second half of 2024.
- **Systemic sclerosis (SSc)**
    - Patient enrollment in the Phase 1/2 RESET-SSc™ trial is ongoing and initial clinical data from the trial are expected in the second half of 2024.

Neurology Portfolio

- **Generalized myasthenia gravis (gMG)**
    - Patient enrollment in the Phase 1/2 RESET-MG™ trial is ongoing and initial clinical data from the trial are expected in the second half of 2024.

Dermatology Portfolio

- Pemphigus vulgaris (PV)
    - Cabaletta is working with active clinical sites to incorporate the RESET-PV™ sub-study within the Phase 1 DesCAARTes™ trial following the submission of a protocol amendment. The RESET-PV sub-study will evaluate CABA-201 as a monotherapy without preconditioning in patients with mucosal PV (mPV) and mucocutaneous PV (mcPV).

External Scientific Presentations and Publications

- In May 2024, Cabaletta's manuscript on the preclinical characterization of CABA-201 titled "Preclinical specificity and activity of a fully human 4-1BB expressing anti-CD19 CART therapy for treatment-resistant autoimmune disease" was published in *Molecular Therapy Methods & Clinical Development*. The preclinical data support the evaluation of CABA-201 for clinical development in patients with autoimmune diseases and were included within the Investigational New Drug submissions for CABA-201.
- In June 2024, Cabaletta presented positive initial clinical data from each of the first two patients dosed with CABA-201 in the RESET-Myositis and RESET-SLE trials at a EULAR European Congress of Rheumatology 2024 Industry Symposia session titled "Immune Reset: The Potential of CAR T Cell Therapy to Transform the Treatment of Patients with Autoimmune Disease" in Vienna, Austria. The initial clinical data demonstrated:
    - CABA-201 was generally well-tolerated with no serious adverse events reported for either patient through the follow-up period.
    - CABA-201 exhibited its anticipated profile of CAR T cell expansion and contraction with complete B cell depletion observed in both patients by day 15 post-infusion.
    - Improvements in both patients' specific disease measures, consistent with the academic experience of a similar 4-1BB CD19-CAR T, suggest a potential emerging clinical benefit with CABA-201.
    - Immature, naïve B cell repopulation in first IMNM patient observed at week 8 is consistent with a potential immune system reset.

Chimeric AutoAntibody Receptor T (CAART) cells Strategy

- **DSG3-CAART:** Cabaletta is evaluating desmoglein 3 chimeric autoantibody receptor T (DSG3-CAART) cells as a potential treatment for patients with mPV. The DesCAARTes trial is no longer dosing patients with DSG3-CAART after evaluation of clinical and translational data from the combination cohort, where patients were pre-treated with IVIg, cyclophosphamide and fludarabine prior to DSG3-CAART infusion.
- **MuSK-CAART:** Cabaletta is evaluating muscle-specific kinase (MuSK) chimeric autoantibody receptor T (MuSK-CAART) cells as a potential treatment for patients with MuSK-associated myasthenia gravis (MuSK MG). Based on review of the initial clinical data and the data from the DSG3-CAART trial, the MusCAARTes™ trial is currently dosing patients in the A2 cohort, where patients are treated with MuSK-CAART without preconditioning.

Manufacturing Leadership and Strategy Updates

- In June 2024, Sarah Yuan, Ph.D., joined the Company as Chief Technology Officer. Dr. Yuan possesses over 20 years of experience in process development and manufacturing strategy leadership in the life sciences industry and most recently served as Chief Technical Operations Officer at Sigilon Therapeutics, Inc., a wholly owned subsidiary of Eli Lilly & Co. Prior to that, Dr. Yuan was Vice President of Process and Analytical Development at bluebird bio and 2seventy bio, where she was instrumental in the regulatory approval process for Abecma™ and two additional cell therapy medicines. Dr. Yuan reports to Gwendolyn Binder, Ph.D., President of Science and Technology of Cabaletta, and is responsible for the process and analytical development, manufacturing strategy, and supply chain operations, in addition to supporting CMC quality control.
- In July 2024, Cabaletta entered into a new manufacturing agreement with Lonza, a leading Contract Development and Manufacturing Organization (CDMO). Under the terms of the agreement, a technology transfer of the manufacturing process for CABA-201 will be performed from Cabaletta to Lonza in anticipation of being able to supply Good Manufacturing Practices (GMP) products to support any of Cabaletta's current and planned clinical trials that evaluate CABA-201, including potential late-stage clinical trials and commercial readiness activities forCABA-201.
- In August 2024, Cabaletta expanded its original November 2023 partnership with Cellares, the first Integrated Development and Manufacturing Organization (IDMO) dedicated to clinical and industrial-scale cell therapy manufacturing, following a successful initial proof-of-concept technology transfer process for the manufacture of CABA-201 using the Cell Shuttle™. The expanded partnership facilitates the potential to incorporate Cellares' manufacturing platform in the CABA-201 clinical program.

Second Quarter 2024 Financial Results

- Research and development expenses were $23.4 million for the three months ended June 30, 2024, compared to $11.8 million for the same period in 2023.
- General and administrative expenses were $6.9 million for the three months ended June 30, 2024, compared to $4.1 million for same period in 2023.
- As of June 30, 2024, Cabaletta had cash, cash equivalents and short-term investments of $203.2 million, compared to $241.2 million as of December 31, 2023.

The Company expects that its cash, cash equivalents and short-term investments as of June 30, 2024, will enable it to fund its operating plan into the first half of 2026.

About CABA-201

CABA-201 is designed to deeply and transiently deplete CD19-positive cells following a one-time infusion, which may enable an "immune system reset" with the potential for durable remission without chronic therapy in patients with autoimmune diseases. Cabaletta is evaluating CABA-201 in multiple autoimmune conditions within five disease-specific company sponsored INDs including myositis (idiopathic inflammatory myopathy, or IIM), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), generalized myasthenia gravis (gMG), and pemphigus vulgaris (PV; a sub-study to evaluate CABA-201 without preconditioning).

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies that have the potential to provide a deep and durable, perhaps curative, treatment for patients with autoimmune diseases. The CABA™ platform encompasses two strategies: the CARTA (chimeric antigen receptor T cells for autoimmunity) strategy, with CABA-201, a 4-1BB-containing fully human CD19-CAR T, as the lead product candidate being evaluated in the RESET™ (REstoring SElf-Tolerance) clinical trials in myositis, systemic lupus erythematosus, systemic sclerosis, generalized myasthenia gravis and in the RESET-PV™ sub-study within the DesCAARTes™ clinical trial in pemphigus vulgaris, along with the CAART (chimeric autoantibody receptor T cells) strategy, with multiple clinical-stage candidates, including DSG3-CAART for mucosal pemphigus vulgaris and MuSK-CAART for MuSK-associated myasthenia gravis. The expanding CABA™ platform is designed to develop potentially curative therapies that offer deep and durable responses for patients with a broad range of autoimmune diseases. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA.

Forward-Looking Statements

This press release contains "forward-looking statements" of Cabaletta Bio within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding: Cabaletta's ability to grow its autoimmune pipeline; Cabaletta's business plans and objectives as a whole; Cabaletta's ability to realize its vision of launching the first curative targeted cell therapy for patients with autoimmune diseases; Cabaletta's ability to successfully complete research and further development and commercialization of its drug candidates in current or future indications; the uncertainties inherent in clinical testing and accruing patients for clinical trials; the timing and results of Cabaletta's clinical trials, as well as its ability to conduct and complete clinical trials; expectation that clinical results will support CABA-201's safety and activity profile; statements regarding the expectations of trial modifications and prophylactic measures, continued trial operations; statements regarding the timing of regulatory filings and interactions with regulatory authorities, including such authorities' review of safety information from Cabaletta's ongoing clinical trials; Cabaletta's ability to retain and recognize and its expectations around the intended incentives conferred by Fast Track Designation for CABA-201 for the treatment of multiple autoimmune diseases; Cabaletta's expectations around the potential success and therapeutic benefits of CABA-201, including its belief that CABA-201 may enable an "immune system reset" with the potential for durable remission without chronic therapy in patients with autoimmune diseases; the Company's advancement of separate Phase 1/2 clinical trials of CABA-201 in patients with SLE, myositis, SSc and gMG and advancement of a RESET-PV sub-study within the ongoing DesCAARTes trial in PV, including updates related to status, safety data, or otherwise and the expected timing of the related data read-outs; Cabaletta's ability to accelerate its pipeline, develop meaningful therapies for patients and leverage its research and translational insights and its expanding manufacturing partnerships; Cabaletta's ability to execute its manufacturing strategy to enable expansion of clinical supply and efficiently scale commercial supply for CABA-201; Cabaletta's planned additional clinical data read-out for patients with myositis and SLE treated with CABA-201; Cabaletta's planned initial clinical data read-outs for patients with SSc and gMG treated with CABA-201 or otherwise; Cabaletta's ability to increase enrollment from its rapidly expanding clinical network in the RESET clinical program; Cabaletta's planned assessment of its DesCAARTes™ and MusCAARTes™ trials; use of capital, expense and other financial results in the future; ability to fund operations into the first half of 2026 and the anticipated contribution of the members of Cabaletta's executives to the company's operations and progress.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks related to regulatory filings and potential clearance; the risk that signs of biologic activity or persistence may not inform long-term results; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of CABA-201; the risk that the results observed with the similarly-designed construct employed in academic publications, including due to the dosing regimen, are not indicative of the results we seek to achieve with CABA-201; risks that modifications to trial design or approach may not have the intended benefits and that the trial design may need to be further modified; risks related to clinical trial site activation, delays in enrollment generally or enrollment rates that are lower than expected; delays related to assessment of clinical trial results; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions and public health crises; Cabaletta's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation and Fast Track Designation or other designations for its product candidates, as applicable; risks related to Cabaletta's ability to protect and maintain its intellectual property position; risks related to fostering and maintaining successful relationships with Cabaletta's collaboration and manufacturing partners, including in light of recent legislation; uncertainties related to the initiation and conduct of studies and other development requirements for its product candidates; the risk that any one or more of Cabaletta's product candidates will not be successfully developed and/or commercialized; and the risk that the initial or interim results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Cabaletta's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Cabaletta's most recent annual report on Form 10-K as well as discussions of potential risks, uncertainties, and other important factors in Cabaletta's other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

CABALETTA BIO, INC.
SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	unaudited		unaudited	
Operating expenses:				
Research and development	$ 23,427	$ 11,797	$ 45,381	$ 24,232
General and administrative	6,852	4,093	12,929	8,614
Total operating expenses	30,279	15,890	58,310	32,846
Loss from operations	(30,279)	(15,890)	(58,310)	(32,846)
Other income:				
Interest income	2,677	1,403	5,661	2,505
Net loss	(27,602)	(14,487)	(52,649)	(30,341)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.56)	$ (0.37)	$ (1.07)	$ (0.81)

Selected Balance Sheet Data

	June 30, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents and investments	$203,225	$ 241,249
Total assets	217,418	253,650
Total liabilities	17,899	17,452
Total stockholders' equity	199,519	236,198

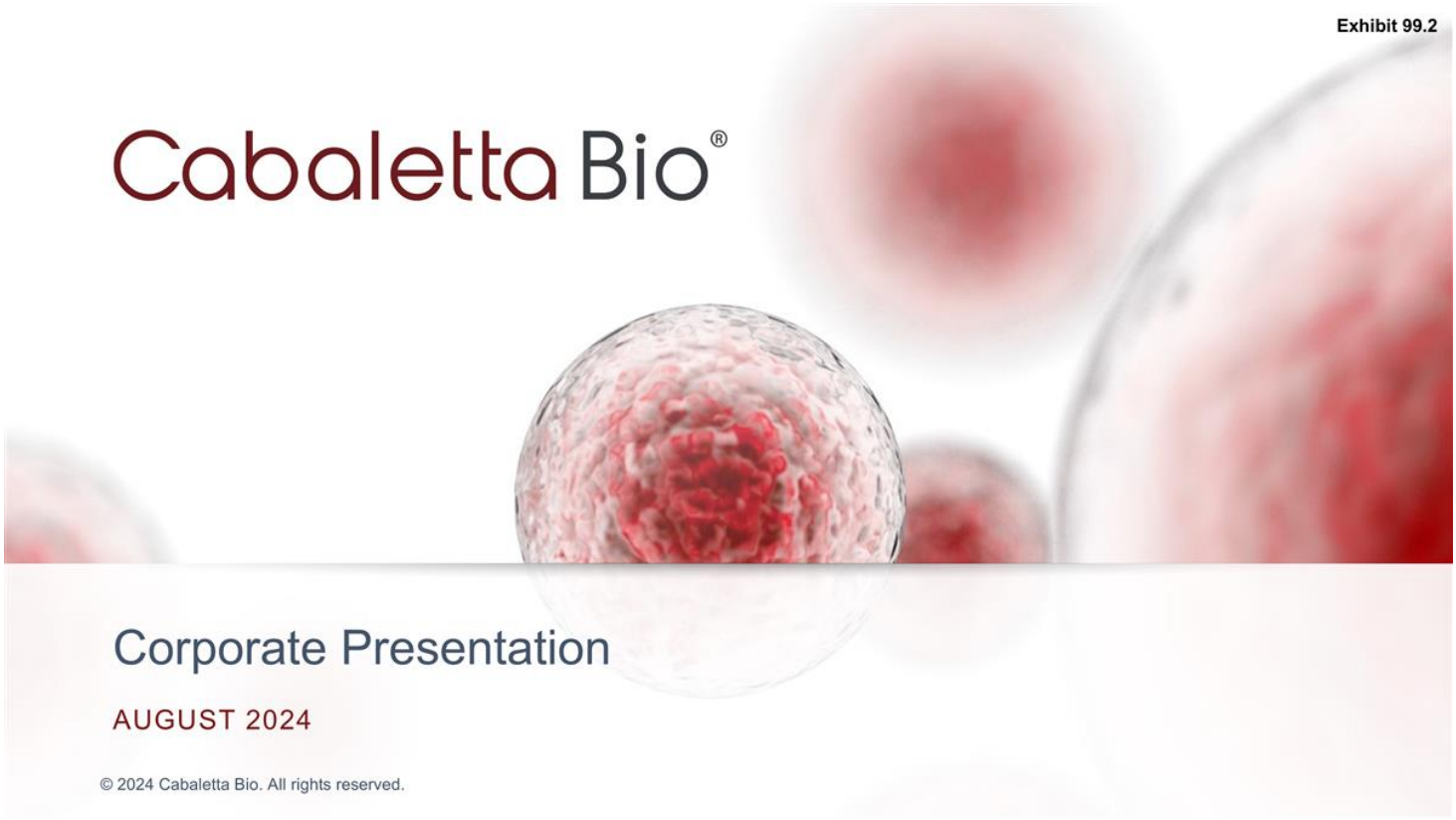
Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

William Gramig
Precision AQ
william.gramig@precisionaq.com

Exhibit 99.2

Cabaletta Bio®



Corporate Presentation

AUGUST 2024

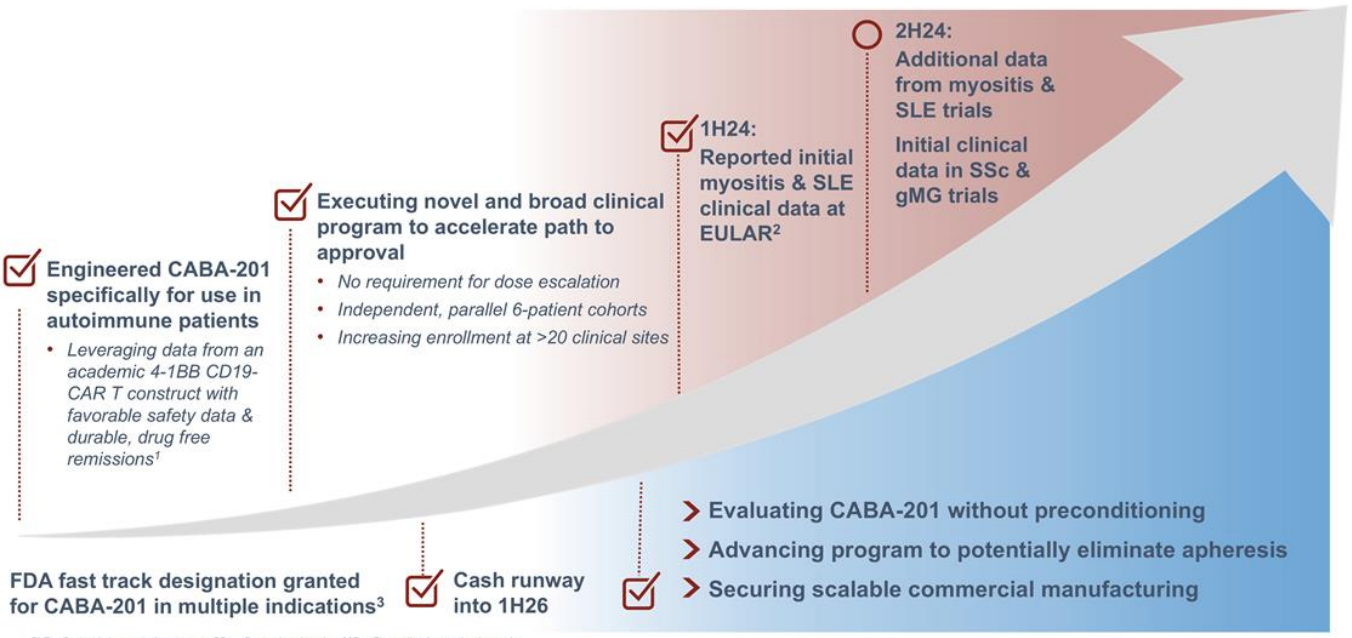
Disclaimer

The following presentation, including any printed or electronic copy of these slides, the talks given by the presenters, the information communicated during any delivery of the presentation and any question and answer session and any document or material distributed at or in connection with the presentation (collectively, the "Presentation") has been prepared by Cabaletta Bio, Inc. ("we," "us," "our," "Cabaletta" or the "Company") and is made for informational purposes only. This Presentation does not purport to be a prospectus, to be complete or to contain all of the information you may desire. Statements contained herein are made as of the date of this Presentation unless stated otherwise, and this Presentation shall not under any circumstances create an implication that the information contained herein is correct as of any time after such date or that information will be updated or revised to reflect information that subsequently becomes available or changes occurring after the date hereof. This Presentation may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial conditions, and include, but are not limited to, express or implied statements regarding our current beliefs, expectations and assumptions regarding: our business, future plans and strategies for our CAAR T and CARTA technologies; our ability to grow our autoimmune-focused pipeline; the ability to capitalize on and potential benefits resulting from our research and translational insights; including those related to any similarly-designed constructs or dosing regimens; the anticipated market opportunities for CABA-201 in patients with autoimmune diseases; the Company's business plans and objectives; our expectations around the potential success and therapeutic benefits of CABA-201, including our belief that CABA-201 may enable an "immune system reset"; Cabaletta's belief of the potential for CAR T to enable a paradigm shift in autoimmunity, including its potential achieve durable remissions without chronic therapy; our plans for Phase 1/2 clinical trials of CABA-201 in patients with systemic lupus erythematosus (SLE), myositis, SSc, and generalized myasthenia gravis (gMG), and for advancement of a RESET-PV sub-study within the ongoing DesCAARTes trial in PV, including the timing thereof, including our anticipated progress, timing of enrollment, expectations for the efficiency of trial designs, updates related to status, safety data, or otherwise and the expected timing of the related data read-outs, and ability to leverage our experience in autoimmune cell therapy; our ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and advance the trial as planned in our Phase 1/2 clinical trials of CABA-201; the timing any planned regulatory filings for our development programs, including IND applications; the progress and results of our MusCAARTes™ Phase 1 trial, including the significance and impact around reported safety and clinical and translational data of cohorts from our MusCAARTes™ Phase 1 trial; Cabaletta's potential to eliminate the need for apheresis by using a simpler collection process to obtain the starting material for the CABA-201 manufacturing process the therapeutic potential and clinical benefits of our product candidates; the expectation that Cabaletta may improve outcomes for patients suffering from SLE, SSc, myositis, gMG, mucosal pemphigus vulgaris, MuSK myasthenia gravis, or other autoimmune diseases; the ability of our clinical strategy to reduce risk, maximize reach and accelerate timelines of our Phase 1/2 clinical trials of CABA-201; expectation that clinical results will support CABA-201's safety and activity profile; statements regarding the timing of regulatory filings and interactions with regulatory authorities, including such authorities' review of safety information from our ongoing clinical trials; our ability to successfully complete our preclinical and clinical studies for our product candidates, including our ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; our ability to obtain and maintain regulatory approval of our product candidates, including our expectations regarding the intended incentives conferred by and ability to retain Orphan Drug Designation and Fast Track Designations for our product candidates, as applicable; our ability to accelerate our pipeline and to develop meaningful therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on our development programs; our ability to contract with third-party suppliers and manufacturers and retain such manufacturers, whether due to legislative action or otherwise; to implement an enhanced manufacturing process and further develop our internal manufacturing strategy, capabilities and facilities; our ability to execute its manufacturing strategy to enable expansion of clinical supply and efficiently scale commercial supply for CABA-201; our potential commercial opportunities, including value and addressable market, for our product candidates; and our expectations regarding our use of capital and other financial results, including our ability to fund operations into the first half of 2026. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements.

Various risks, uncertainties and assumptions could cause actual results to differ materially from those anticipated or implied in our forward-looking statements. Such risks and uncertainties include, but are not limited to, risks related to the success, cost, and timing of our product candidate development activities and preclinical studies and clinical trials, risks related to our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in our preclinical studies and clinical trials of CABA-201 and MuSK-CAART, the risk that the results observed with the similarly-designed construct, including, but not limited to, due to dosing regimen, are not indicative of the results we seek to achieve with CABA-201, the risk that signs of biologic activity or persistence may not inform long-term results, the risk that persistence observed with effective CD19-CAR T oncology studies in combination with lymphodepletion is not indicative of, or applicable to, clinical responses in patients with mPV, risks related to clinical trial site activation or enrollment rates that are lower than expected, our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of CABA-201; risks that modifications to trial design or approach may not have the intended benefits and that the trial design may need to be further modified; our ability to protect and maintain our intellectual property position, risks related to our relationships with third parties, uncertainties related to regulatory agencies' evaluation of regulatory filings and other information related to our product candidates, our ability to retain and recognize the intended incentives conferred by any Orphan Drug Designations and Fast Track Designations, risks related to regulatory filings and potential clearance, the risk that any one or more of our product candidates will not be successfully developed and commercialized, the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies, and risks related to volatile market and economic conditions and public health crises. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ materially from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our other and subsequent filings with the Securities and Exchange Commission. Certain information contained in this Presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this Presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. The Company is the owner of various trademarks, trade names and service marks. Certain other trademarks, trade names and service marks appearing in this Presentation are the property of third parties. Solely for convenience, the trademarks and trade names in this Presentation are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Cabaletta Bio®

Realizing the vision to transform autoimmune disease treatment

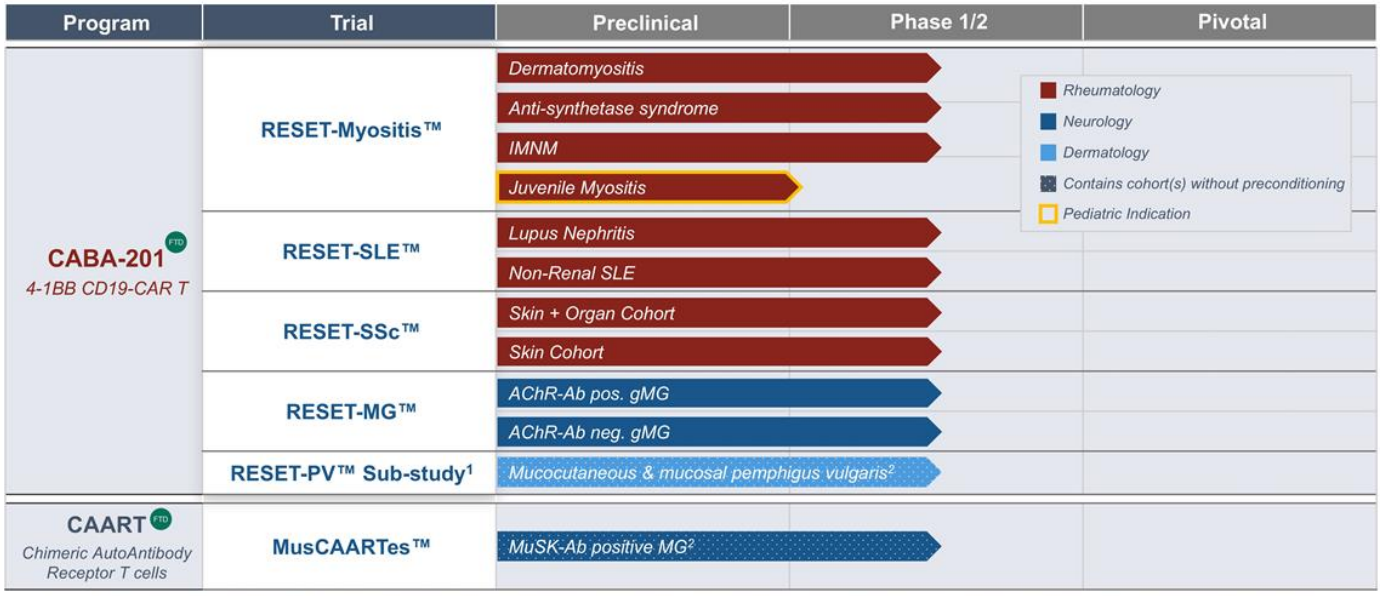


SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis

1. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." New England Journal of Medicine 390.8 (2024): 687-700. The construct utilized in these studies has a similar design to CABA-201, sharing the 4-1BB costimulatory domain, but is a different construct.
2. Data cut-off as of 28 May 2024.
3. FDA Fast Track Designation received in dermatomyositis, SLE, lupus nephritis and systemic sclerosis.

Pipeline targeting autoimmune diseases with high unmet need

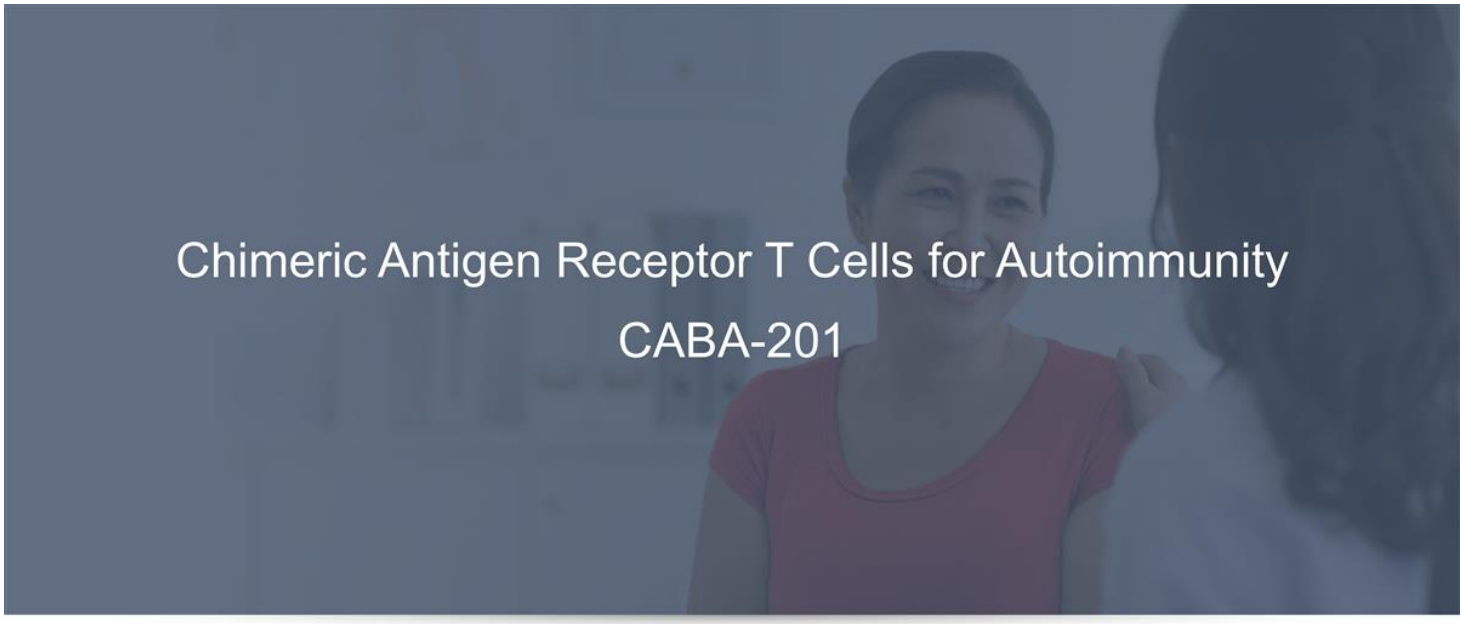
Innovative and scalable clinical strategy with potential for accelerated development path



RESET™ – **RE**storing **SE**lf-**T**olerance; IMNM – Immune-mediated necrotizing myopathy; SLE – Systemic lupus erythematosus; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis

1. Sub-study incorporated into DesCAARTes™ study. 2. Currently being evaluated in a Phase 1 trial.

● FDA Fast Track Designation received in dermatomyositis, SLE and lupus nephritis, systemic sclerosis, mucosal pemphigus vulgaris, and MuSK-Ab positive MG.



Cabaletta Bio®

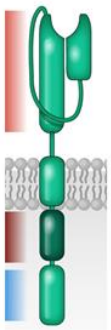
CABA-201: CD19-CAR T specifically designed for autoimmunity

Cabaletta's CD19 binder with similar *in vitro* & *in vivo* activity to FMC63[1,2] (binder used in academic report[3])

Fully human anti-CD19 binder
Similar binding affinity & biologic activity to FMC63, with binding to the same epitopes[1,2]

4-1BB costimulatory domain
Same co-stim. domain as used in academic studies

CD3-zeta signaling domain



CABA-201[5]

Clinical data reported by IASO using licensed CD19 binder in oncology[4]

- **Fully human binder**
  Evaluated as dual-CAR combined with CD22 binder with standard Flu/Cy preconditioning
- **Data reported in ~20 patients to date**
  B cell leukemia and lymphoma in IIT in China
- **Safety data supports autoimmune development**

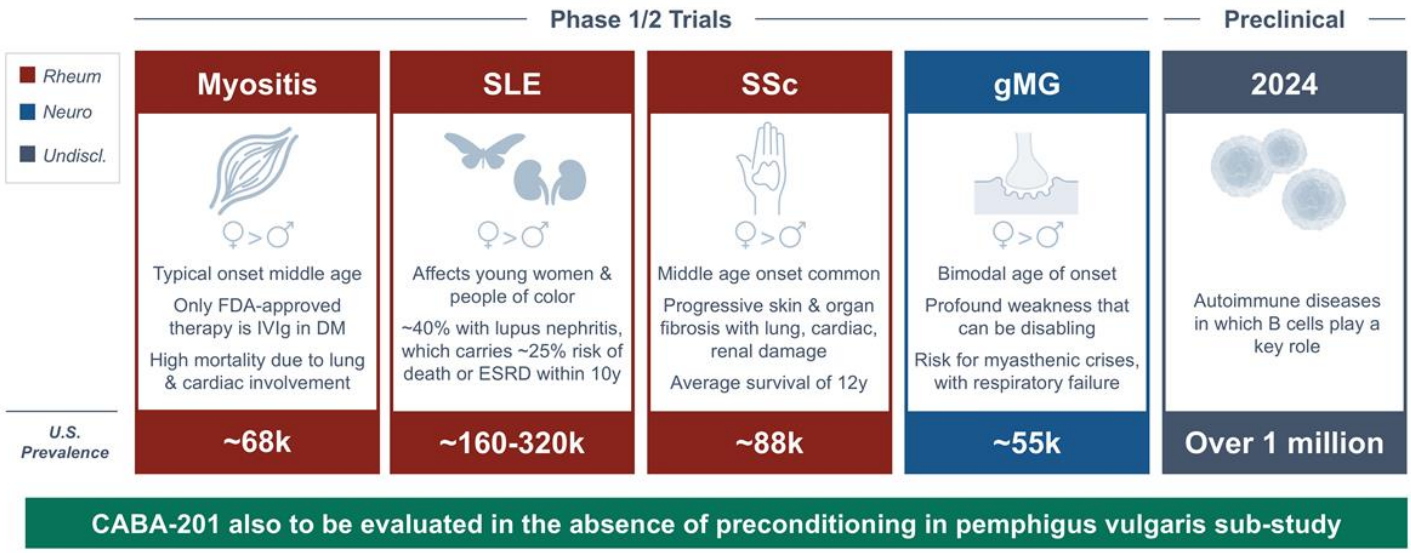
IIT – Investigator-initiated trial; Flu/Cy – Fludarabine/Cyclophosphamide

1. Peng, Binghao J, et al. "Preclinical specificity and activity of CABA-201, a fully human 4-1BB containing CD19 CAR T therapy for treatment-resistant autoimmune disease." Poster presented at: American Society Gene and Cell Therapy 26th Annual Meeting; 2023 May 19; Los Angeles, CA.
2. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human anti-CD19 chimeric antigen receptors for T-cell therapy." Journal of Cellular Physiology 236.8 (2021): 5832-5847.
3. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." New England Journal of Medicine 390.8 (2024): 687-700.
4. Evaluated as part of CT120, a dual-CD19xCD22 CAR T product candidate under development by Nanjing IASO Biotherapeutics, Co., Ltd. (IASO Bio).
5. Transmembrane domain in CABA-201 is CD8α vs. TNFRSF19 (Troy) utilized in the academic construct. The two transmembrane domains have not been shown to have a significant difference in function or IFN-γ production in preclinical studies. The CD8α transmembrane domain is employed in tisagenlecleucel.

CABA-201

REstoring SElf-Tolerance (RESET™) Phase 1/2 trials advancing

SLE & myositis trials currently enrolling, with a broadening portfolio to realize the potential of CABA-201



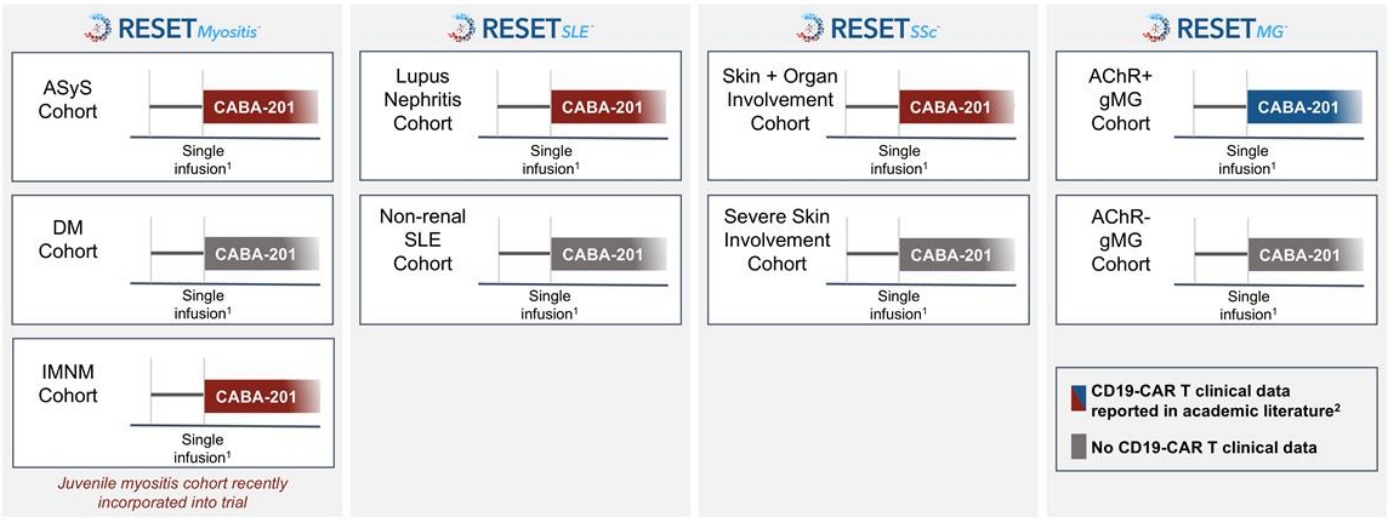
CABA-201 also to be evaluated in the absence of preconditioning in pemphigus vulgaris sub-study

SLE – Systemic lupus erythematosus; DM – Dermatomyositis; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis; ESRD – End-stage renal disease

CABA-201

Clinical strategy to reduce risk, maximize reach & accelerate timelines

Broad investigation of CABA-201 in well-defined patient populations with the same dose & similar design



Each cohort to include 6 patients treated with an identical dose – without dose escalation requirement – and designed to inform discussions with FDA on registrational path for each indication

SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis; ASyS – Anti-synthetase syndrome; DM – Dermatomyositis; IMNM – Immune-mediated necrotizing myopathy

1. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to a single dose CABA-201, followed by short inpatient stay.
2. The data reported in the academic literature does not employ CABA-201.

RESET-Myositis™: Phase 1/2 study design for CABA-201

Initial data presented at EULAR 2024 Congress; enrolling patients with active myositis with DM, ASyS or IMNM

Screening

Key inclusion criteria

- Adults 18-75y with a clinical IIM diagnosis
- Subtype based on serology
- Evidence of active disease despite standard of care

Key exclusion criteria

- Cancer associated myositis
- Significant lung or cardiac impairment
- B cell-depleting agent within prior ~6 months
- Previous CAR T cell therapy and/or HSCT

Phase 1/2 Study Design

Open-label trial with parallel 6-subject cohorts

CABA-201
DM — *Single dose of 1x10⁶ cells/kg[1]*

CABA-201
ASyS — *Single dose of 1x10⁶ cells/kg[1]*

CABA-201
IMNM — *Single dose of 1x10⁶ cells/kg[1]*

Equivalent to dose of 4-1BB CD19-CAR T used in academic report along with standard preconditioning[1,2]

Study Objectives

Primary objective

Safety & tolerability within 28 days of infusion

Categories of key secondary objectives

- **Myositis clinical activity**
- **CK / muscle enzymes**
- **Myositis-specific autoantibody levels**
- **Adverse events**
- **PK / PD analysis**

Juvenile idiopathic inflammatory myopathy (JIIM, juvenile myositis) cohort recently incorporated into trial

IIM – Idiopathic inflammatory myopathy; DM – Dermatomyositis; ASyS – Anti-synthetase syndrome; IMNM – Immune-mediated necrotizing myopathy; CK – creatine kinase

1. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to a single dose CABA-201, followed by short inpatient stay.
2. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." New England Journal of Medicine 390.8 (2024): 687-700.

RESET-SLE™: Phase 1/2 study design for CABA-201

Initial data presented at EULAR 2024 Congress; enrolling patients with active SLE with or without renal disease

Screening

Key inclusion criteria

- Adults 18-65y with an SLE diagnosis
- Confirmatory serology
- SLE: active, moderate to severe SLE, SLEDAI 2K ≥8 despite standard therapy
- LN: active, biopsy-proven LN class III or IV, ± class V

Key exclusion criteria

- B cell-depleting agent within prior ~6 months
- Presence of kidney disease other than LN
- Previous CAR T cell therapy and/or HSCT

Phase 1/2 Study Design

Open-label trial with parallel 6-subject cohorts

SLE with lupus nephritis — **CABA-201** — *Single dose of 1x10⁶ cells/kg[1]*

SLE without renal disease — **CABA-201** — *Single dose of 1x10⁶ cells/kg[1]*

Equivalent to dose of 4-1BB CD19-CAR T used in academic report along with standard preconditioning[1,2]

Study Objectives

Primary objective

Safety & tolerability within 28 days of infusion

Categories of key secondary objectives

- **SLE disease activity**
- **Complete renal response**
- **Adverse events**
- **PK / PD analysis**
- **Biomarker analyses**

Similarly designed Phase 1/2 trials – RESET-SSc™ & RESET-MG™ – advancing in SSc & gMG

SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis

1. Subjects will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to a single dose CABA-201, followed by short inpatient stay.
2. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." New England Journal of Medicine 390.8 (2024): 687-700.

CABA-201

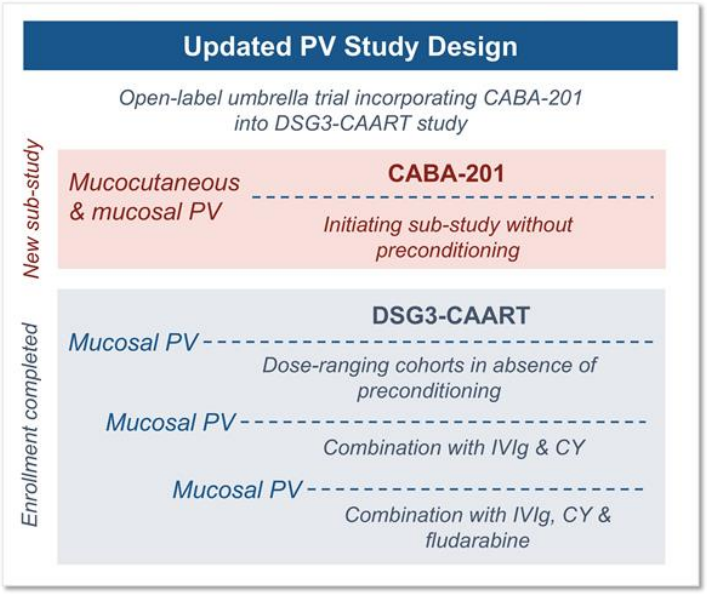
Evaluating CABA-201 without preconditioning in pemphigus

Elimination of preconditioning may expand CAR T opportunity for autoimmune patients

- Published data in multiple myeloma suggests preconditioning may not be necessary[1]
- Experience with and without preconditioning in PV in DesCAARTes™ study

As a well-defined autoantibody-mediated disease, PV is a potentially ideal evaluation setting

- Anti-DSG antibodies necessary & sufficient for disease
- Anti-DSG antibodies 98-100% sensitive & specific[2]
- Anti-DSG antibodies correlate with disease activity
- Depletion of B cells or antibodies improve disease
- Clinical scoring based on mucosal & skin disease

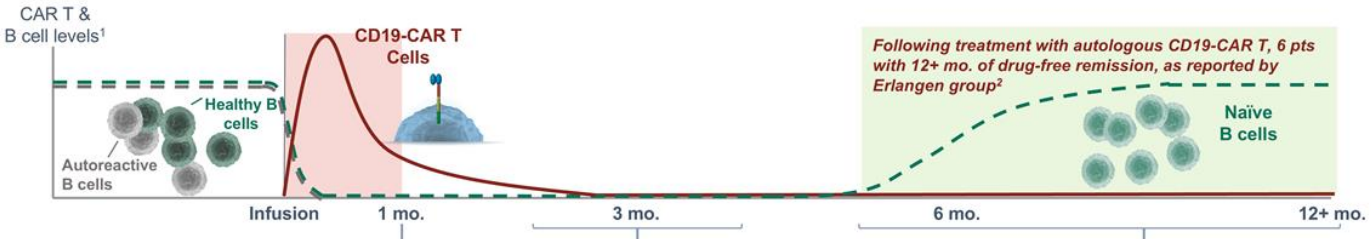


DSG – Desmoglein; PV – Pemphigus vulgaris

1. Cohen, Adam D., et al. "B cell maturation antigen–specific CAR T cells are clinically active in multiple myeloma." The Journal of Clinical Investigation 129.6 (2019).
2. Schmidt, Enno, et al. "Novel ELISA systems for antibodies to desmoglein 1 and 3." Experimental dermatology 19.5 (2010): 458-463.

Metrics to assess outcomes of B cell depletion in autoimmunity

Translational & clinical parameters inform framework to evaluate advanced modalities in autoimmunity



Metrics of evaluation	Within 1 month	~3 months	Up to 12+ months
Translational measures	✓ B cell depletion: Timing & depth ✓ CAR T expansion: Magnitude & timing	✓ Autoantibody changes ✓ Vaccine titer changes ✓ Inflammatory marker changes	✓ Time to B cell repopulation ✓ B cell phenotype[3] ❑ Autoantibody changes
Clinical data	✓ Rate of CRS more severe than fever ✓ Rate & grade of ICANS ✓ Rate & severity of infection	✓ Early efficacy signals ✓ Rate & severity of infection	❑ Durability of clinical activity ❑ Rate & severity of infection ❑ Delayed cytopenias
Patient experience	✓ Hospitalization requirements ✓ Apheresis & preconditioning ✓ Single vs. multiple infusions	✓ Chronic maintenance therapy / concomitant medications, if any	❑ Chronic maintenance / concomitant medications, if any

✓ Indicates data presented at EULAR 2024 for either or both of the first two patients in the RESET clinical program.

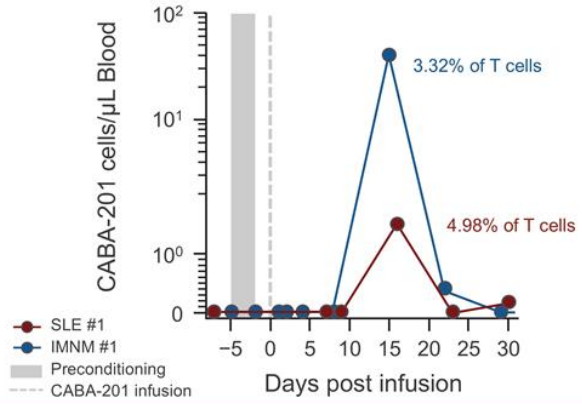
1. Illustrative graphic, adapted from Taubmann, J., et al. "OP0141 Long Term Safety and Efficacy Of CAR-T Cell Treatment in Refractory SLE-Data from the First Seven Patients." (2023): 93-94.
2. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." New England Journal of Medicine 390.8 (2024): 687-700.
3. Flow phenotyping data; confirmatory analyses ongoing.

IMNM #1 SLE #1

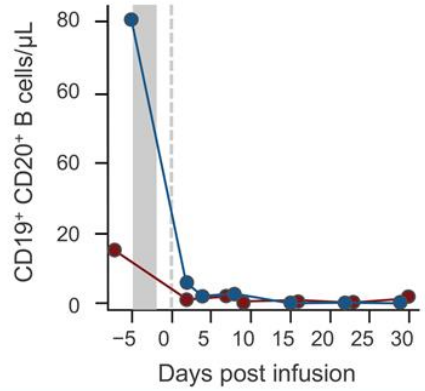
CABA-201 demonstrated expansion & targeted B cell depletion

CABA-201 exhibited anticipated profile of expansion and contraction[1]

Expansion of CAR T cells to anticipated range suggests target engagement



Complete B cell depletion achieved by day 15 on flow cytometry



Peripheral peak CAR T expansion occurred at approximately 2 weeks & rapid contraction suggests systemic B cell aplasia was achieved

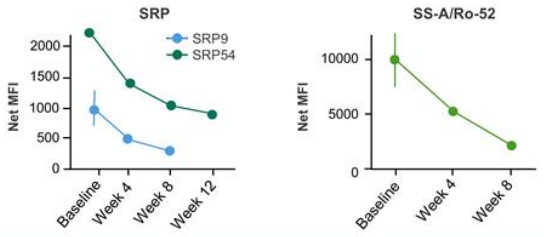
1. Response appears to be consistent with published data of cryopreserved CAR T products as well as the expansion profile of BCMA-CAR T products in patients with multiple myeloma, in which the number of target cells is more similar to autoimmune disease than to B cell leukemias and lymphomas.[2-6]
2. Shah BD, et al. *Lancet*. 2021;398(10299):491-502.
3. Awasthi R, et al. *Blood Adv*. 2020;4(3):560-572.
4. Munshi NC, et al. *N Engl J Med*. 2021;384(8):705-716.
5. Cohen AD, et al. *Blood Cancer J*. 2022;12(2):32.
6. Müller F, et al. *N Engl J Med*. 2024;390(8):687-700.

CK reduction & clinical improvement observed in SRP IMNM

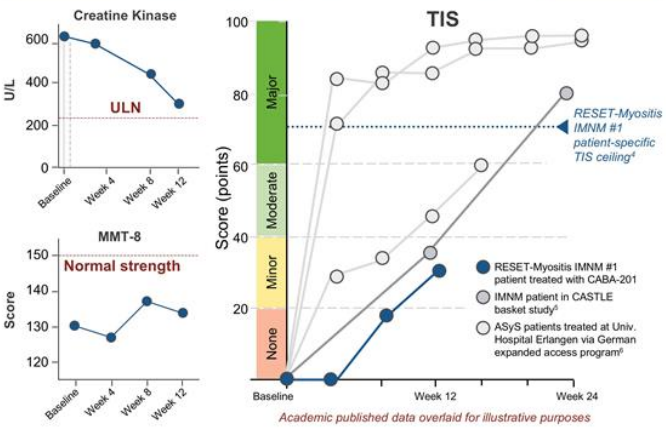
Antibody reduction & clinical improvement in disease activity observed with follow-up of 12 weeks[1]

- Discontinued all disease-specific therapies
- Disease markers continuing to trend positively
- Patient reported symptoms as much improved

Quantitative translational assay shows ongoing reduction in SRP & Ro-52 antibodies[2,3]



Disease activity & improvement measures



12-week TIS consistent with IMNM case report[5]

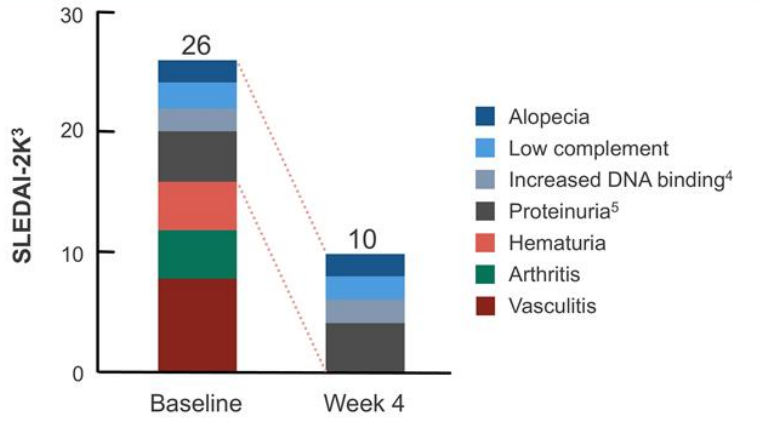
No CRS, ICANS, or infections reported (no tocilizumab received), and the SRP IMNM patient was discharged 4 days post infusion

1. Data cut-off as of May 28, 2024.
2. Luminex assay developed and performed by Cabaletta Labs.
3. Qualitative commercial assay (Myositis Antigen Panel, performed at National Jewish Health Advanced Diagnostic Laboratories) suggests SRP54 antibody remains strongly positive at Week 12; Ro-52 normalizes by week 8.
4. Based on patient's moderate level of muscle disease at baseline, mild-moderate disability and limited extramuscular manifestations, the maximum achievable score is 70 points on the 100-point TIS scale.
5. Patient treated in third-party CASTLE Phase I/II basket study, TIS data at Week 12 and 24 provided via personal communication with and as presented by Dr. Georg Schett at the EULAR 2024 symposium.
6. Müller F, et al. *N Engl J Med.* 2024;390(8):687-700.

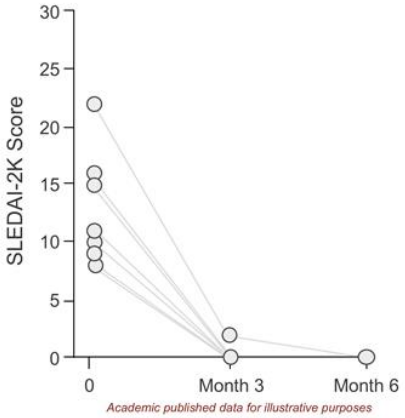
Early efficacy signals in first patient in non-renal SLE cohort[1]

Trend toward improvement in disease manifestations observed with follow up of 4 weeks[2]

SLE patient #1



Academic SLE data[6]



Academic published data for illustrative purposes

Vasculitis, arthritis and hematuria resolved within 4 weeks despite discontinuation of all therapies at infusion other than ongoing taper from prednisone 10mg per day

No CRS, ICANS, or infections reported (no tocilizumab received), and the non-renal SLE patient was discharged 4 days post infusion

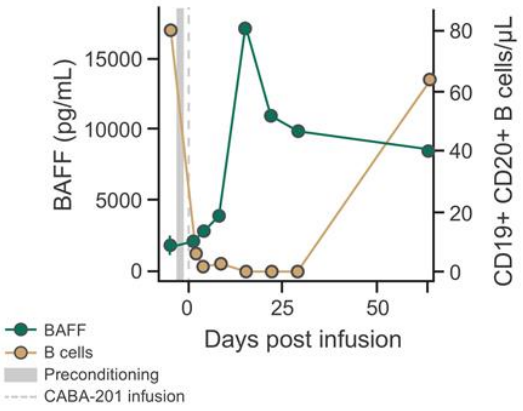
1. Patient in non-renal SLE cohort due to isolated Class V LN.
2. Data cut-off as of 28 May 2024.
3. Baseline and Day 29 SLEDAI-2K score are reflective of disease activity at study visit day.
4. Anti-dsDNA antibody titer decreased from 1:40 to 1:10 from Baseline to Week 4.
5. Urine Protein Creatinine Ratio decreased from 1.08 to 0.80 from Baseline to Week 4.
6. SLE patients treated at Univ. Hospital Erlangen via German expanded access program; Müller F, et al. *N Engl J Med.* 2024;390(8):687-700.

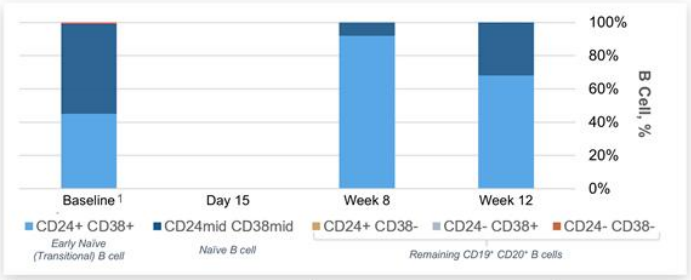
IMNM #1

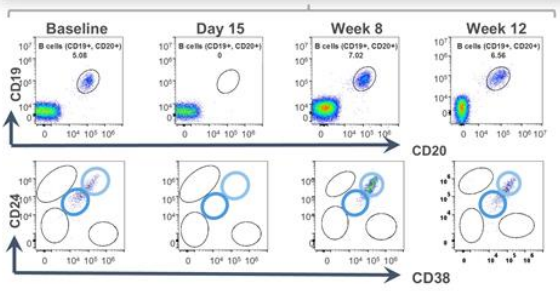
Naïve B cell repopulation occurred at 2 months in first IMNM patient

Initial patient phenotyping data consistent with potential immune system reset; confirmatory analyses ongoing

Systemic B cell depletion triggers BAFF to encourage bone marrow B cell repopulation







B cell phenotyping data

Note: Flow plot gating reflects CD19+ CD20+ live lymphocytes.
1. Data cut-off as of May 28, 2024.

Manufacturing strategy

Staged approach allows for efficient allocation of capital while leveraging experienced partners

Early Phase:
Penn, CDMOs & CABA Process

Ongoing

- **Penn has reliably provided timely product for years**
- **Expanded commercial CDMO partnerships for vector and cell product supply**
- **Process development work on track to implement commercial-ready process in pivotal studies**

Late Phase & Commercial:
Scale-Up & Commercialization

Data-gated, staged investment

- **Evaluating paths to commercial-ready manufacturing:**
  - ✓ **Expansion of CDMO relationships** Lonza
  - ✓ **Opportunities for automated manufacturing** CELLARES
  - **Cabaletta-operated facility**
  - **Strategic partnership(s)**
- **Continuous focus on innovations to address scale**
  - **Internal program**
  - **Cellares technology assessment program advancing**

Securing & expanding our leadership in autoimmune cell therapy

Increased enrollment since EULAR presentation

Advancing the RESET™ clinical trials with the goal of delivering on our commitment to patients

Myositis
Systemic lupus erythematosus
Systemic sclerosis
Generalized myasthenia gravis
Pemphigus vulgaris

- Minimizing the requirement for inpatient stay
- Evaluating CABA-201 without preconditioning
- Seeking to remove the burden of apheresis[1]
- Innovating to address scale in autoimmune disease

Broadening potential to serve patients

Biologic opportunity for potential cure or paradigm-shifting treatment may be possible in dozens of autoimmune diseases

Rheumatology	• Rheumatoid arthritis • ANCA-associated vasculitis • Sjögren's syndrome
Neurology	• Multiple sclerosis • Neuromyelitis optica • CIDP
Nephrology	• Membranous nephropathy • Goodpasture's syndrome
Dermatology	• Pemphigus foliaceus • Epidermolysis bullosa acquisita • Bullous pemphigoid
Hematology	• Immune thrombocytopenic purpura • Thrombotic thrombocytopenic purpura • Antiphospholipid syndrome • Autoimmune hemolytic anemia
Endocrinology	• Type 1 diabetes • Graves' disease • Hashimoto's disease

1. Abstract 1372: Autologous CD19 CART Manufacturing from Whole Blood Collection for the Treatment of Autoimmune Disease. ASGCT 2024.

Cabaletta Bio®

Cabaletta Bio leadership

Track record of operational success evaluating novel cell therapy candidates in autoimmunity

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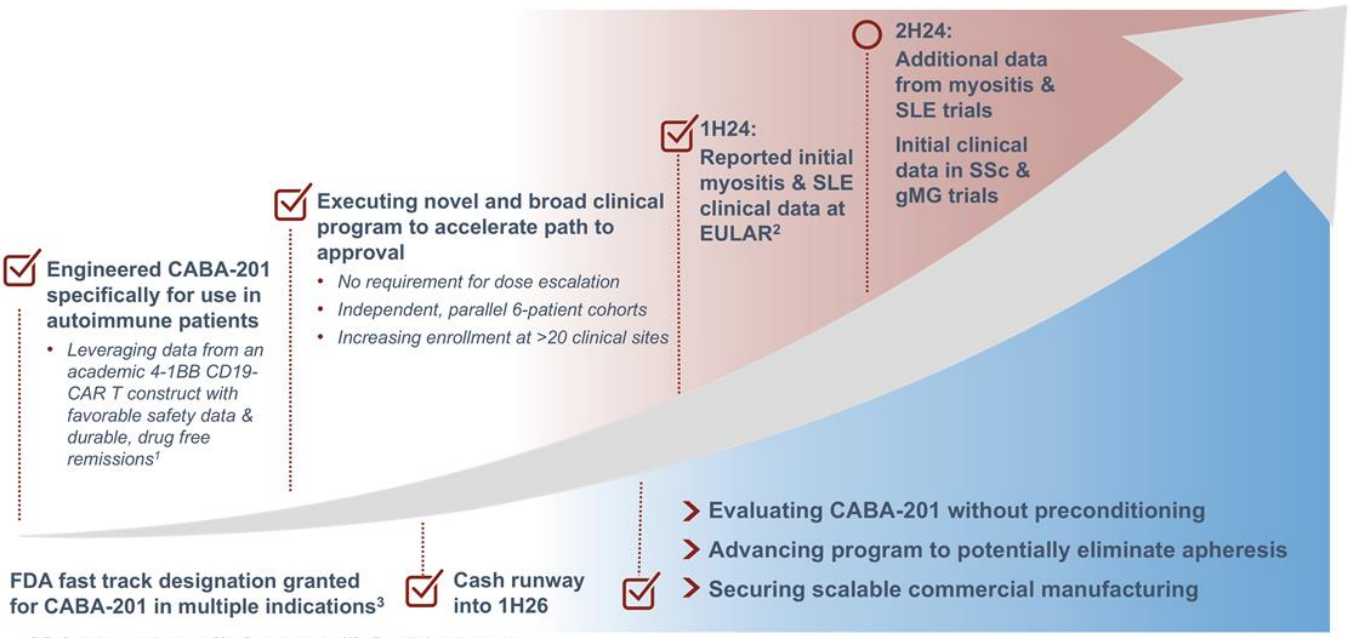
Realizing the vision to transform autoimmune disease treatment



SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis

1. Müller, Fabian, et al. "CD19 CAR T-Cell Therapy in Autoimmune Disease—A Case Series with Follow-up." New England Journal of Medicine 390.8 (2024): 687-700. The construct utilized in these studies has a similar design to CABA-201, sharing the 4-1BB costimulatory domain, but is a different construct.
2. Data cut-off as of 28 May 2024.
3. FDA Fast Track Designation received in dermatomyositis, SLE, lupus nephritis and systemic sclerosis.

Cabaletta Bio®

Corporate Presentation

AUGUST 2024