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

May 15, 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 May 15, 2024, Cabaletta Bio, Inc. (the "Company") announced its financial results for the first quarter ended March 31, 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 2.01 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 May 15, 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 May 15, 2024, furnished herewith.
99.2	Cabaletta Bio, Inc. Corporate Presentation, dated May 15, 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: May 15, 2024

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

Exhibit 99.1

Cabaletta Bio®

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

– No CRS or ICANS of any grade observed during the 28-day DLT observation window for either of the first patients dosed with CABA-201 in the RESET-Myositis™ and RESET-SLE™ trials –

– Initial clinical data from each of the first patients in the RESET-Myositis and RESET-SLE trials to be presented at a satellite symposium at the EULAR 2024 Congress in June –

– Evaluating CABA-201 without preconditioning by initiation of the RESET-PV™ sub-study within the ongoing DesCAARTes™ trial in pemphigus vulgaris –

PHILADELPHIA, May 15, 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 first quarter ended March 31, 2024, and provided a business update.

"With no CRS or ICANS of any grade observed in either of the first patients from the RESET-Myositis and RESET-SLE trials, we look forward to presenting initial translational and clinical data from both patients during a satellite symposium at the EULAR 2024 Congress on June 14th," said Steven Nichtberger, M.D., Chief Executive Officer and Co-founder of Cabaletta. "In addition to implementing our development path for CABA-201, we have made substantial progress on two innovations designed to optimize the patient and physician experience. First, we are evaluating CABA-201 without preconditioning through the incorporation of the RESET-PV sub-study within the ongoing DesCAARTes trial in patients with pemphigus vulgaris, expanding CABA-201 development into dermatology. Second, we demonstrated the potential to eliminate the need for apheresis by using a blood draw to obtain the starting material for the CABA-201 manufacturing process as presented at the ASGCT meeting. We are evaluating the opportunity to incorporate an apheresis-free process into our ongoing CABA-201 clinical program. By executing on our CABA-201 development strategy and integrating these types of innovations, we believe that we are well positioned to deliver on the full potential of the targeted cell therapies that we are developing to provide durable, drug-free remissions for patients with a broad range of 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 a 4-1BB co-stimulatory domain as a potential treatment for a broad range of autoimmune diseases across multiple therapeutic portfolios where B cells contribute to the initiation and/or maintenance of disease.

Rheumatology Portfolio

- **Myositis (idiopathic inflammatory myopathies)**
  - In March 2024, Cabaletta announced the first patient had been dosed in the Phase 1/2 RESET-Myositis trial. No evidence of cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade was observed during the 28-day dose-limiting toxicity (DLT) observation window following administration. Patient enrollment in the Phase 1/2 RESET-Myositis trial is ongoing and initial clinical data from the first patient is anticipated to be presented in a satellite symposium at the EULAR 2024 Congress in June.
  - During the first quarter of 2024, Cabaletta announced that the U.S. Food and Drug Administration (FDA) granted regulatory designations to CABA-201 in myositis, including Fast Track Designation for the treatment of patients with dermatomyositis, Orphan Drug Designation for the treatment of idiopathic inflammatory myopathies (IIM, or myositis) and Rare Pediatric Disease Designation for the treatment of juvenile dermatomyositis.
- **Systemic lupus erythematosus (SLE)**
  - The first patient has been dosed in the Phase 1/2RESET-SLE trial. No evidence of CRS or ICANS of any grade was observed during the 28-day DLT observation window following administration. Patient enrollment in the Phase 1/2RESET-SLE trial is ongoing and initial clinical data from the first patient is anticipated to be presented in a satellite symposium at the EULAR 2024 Congress in June.
  - In March 2024, Health Canada issued a No Objection Letter in response to a Clinical Trial Application for theRESET-SLE trial submitted by Cabaletta, enabling the Company to begin the process to activate clinical trial sites and pursue patient enrollment for the RESET-SLE trial in Canada.
- **Systemic sclerosis (SSc)**
  - During the first quarter of 2024, Cabaletta announced that the FDA granted regulatory designations toCABA-201 in SSc, including Fast Track Designation for the treatment of patients with SSc and Orphan Drug Designation for the treatment of SSc.
  - Cabaletta expects to report initial clinical data from the Phase 1/2RESET-SSc™ trial in the second half of 2024.

Dermatology Portfolio

- **Pemphigus vulgaris (PV)**
  - Cabaletta is working with active clinical sites to incorporate theRESET-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).

Neurology Portfolio

- **Generalized myasthenia gravis (gMG)**
  - Cabaletta expects to report initial clinical data from the Phase 1/2RESET-MG™ trial in the second half of 2024.

Past and Upcoming External Scientific Presentations

- In May 2024, Cabaletta presented new preclinical data at the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting demonstrating the ability to manufacture autologous CD19-CAR T cells from a blood draw as a potential alternative to apheresis. Whole blood collections from 80mL to 200mL were successfully used in lieu of apheresis material to produce CAR T cells that demonstrated similar growth, viability, memory phenotype and cytotoxicity across 3 healthy donors. In addition, CD19-CAR T cells were manufactured successfully from whole blood sourced from 2 lupus patients and showed expected T cell memory subtype and cytotoxic functionality.
- In June 2024, Cabaletta plans to present initial clinical data from each of the first patients treated with CABA-201 in the RESET-Myositis and RESET-SLE trials in 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" at 8:15 a.m. CEST on Friday, June 14, 2024, in Vienna, Austria.

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 not currently dosing patients with DSG3-CAART as we evaluate clinical and translational data from the combination cohort, where patients were pre-treated with IVIg, cyclophosphamide and fludarabine prior to DSG3-CAART infusion, with the aim of improving persistence and activation of DSG3-CAART compared to findings from the no preconditioning cohorts previously reported.
- **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). The MusCAARTes™ trial is not currently dosing patients as we evaluate clinical and translational data from the A1 and A2 cohorts, where patients were treated with MuSK-CAART without preconditioning.

Upcoming Investor Events

Cabaletta plans to participate in the following upcoming investor conferences:

- H.C. Wainwright 2nd Annual BioConnect Investor Conference at NASDAQ, which is being held on May 20, 2024 in New York, NY.
- Jefferies Global Healthcare Conference, which is being held from June 5-6, 2024 in New York, NY.
- Goldman Sachs 45th Annual Global Healthcare Conference, which is being held from June 10-13, 2024 in Miami, FL.

First Quarter 2024 Financial Results

- Research and development expenses were $22.0 million for the three months ended March 31, 2024, compared to $12.4 million for the same period in 2023.
- General and administrative expenses were $6.1 million for the three months ended March 31, 2024, compared to $4.5 million for same period in 2023.
- As of March 31, 2024, Cabaletta had cash, cash equivalents and short-term investments of $223.8 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 March 31, 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 B 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 including systemic lupus erythematosus (SLE), myositis, systemic sclerosis (SSc), generalized myasthenia gravis (gMG) and pemphigus vulgaris (PV). Cabaletta is conducting four Phase 1/2 RESET™ clinical trials evaluating CABA-201 with a total of nine cohorts that can advance simultaneously, employing a similar parallel cohort design and starting dose of 1 x 10^6 cells/kg without a dose escalation requirement. CABA-201 is also being evaluated in the absence of preconditioning in a separate sub-study within the DesCAARTes™ trial for patients with PV.

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 systemic lupus erythematosus, myositis, systemic sclerosis and 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 future plans and strategies for its CAAR T and CARTA technologies and the company's business plans and objectives as a whole; statements regarding regulatory filings for its development programs, including the planned timing of such regulatory filings and potential review by regulatory authorities; Cabaletta's ability to retain and recognize and its expectations around the intended incentives conferred by Fast Track Designation and/or Orphan Drug Designation for CABA-201 for the treatment of multiple autoimmune diseases; Cabaletta's ability to retain and recognize and its expectations around the potential benefits and incentives provided by FDA's rare pediatric disease designation for CABA-201; 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 plans to eliminate the need for apheresis by using a simpler collection process to obtain the starting material for the CABA-201 manufacturing process; Cabaletta's ability to accelerate its pipeline, develop meaningful therapies for patients and leverage its research and translational insights; the Company's expectations for the efficiency of the trial design for its Phase 1/2 clinical trials of CABA-201 and for its RESET-PV sub-study within the ongoing DesCAARTes trial in PV; Cabaletta's planned initial clinical data read-out at the EULAR 2024 Congress in June 2024 for patients with myositis and SLE treated with CABA-201; Cabaletta's additional planned initial clinical data read-outs for patients with SSc and gMG treated with CABA-201 or otherwise; Cabaletta's advancement of the process to activate clinical trial sites and pursue patient enrollment for the RESET-SLE trial in Canada; 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 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 March 31,	
	2024	2023
	Unaudited	
Operating expenses:		
Research and development	$ 21,954	$ 12,435
General and administrative	6,077	4,521
Total operating expenses	28,031	16,956
Loss from operations	(28,031)	(16,956)
Other income:		
Interest income	2,984	1,102
Net loss	(25,047)	(15,854)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.51)	$ (0.45)

Selected Balance Sheet Data

	March 31, 2024	December 31, 2023
	(unaudited)	
Cash, cash equivalents and investments	$223,845	$ 241,249
Total assets	240,457	253,650
Total liabilities	18,737	17,452
Total stockholders' equity	221,720	236,198

Contacts:

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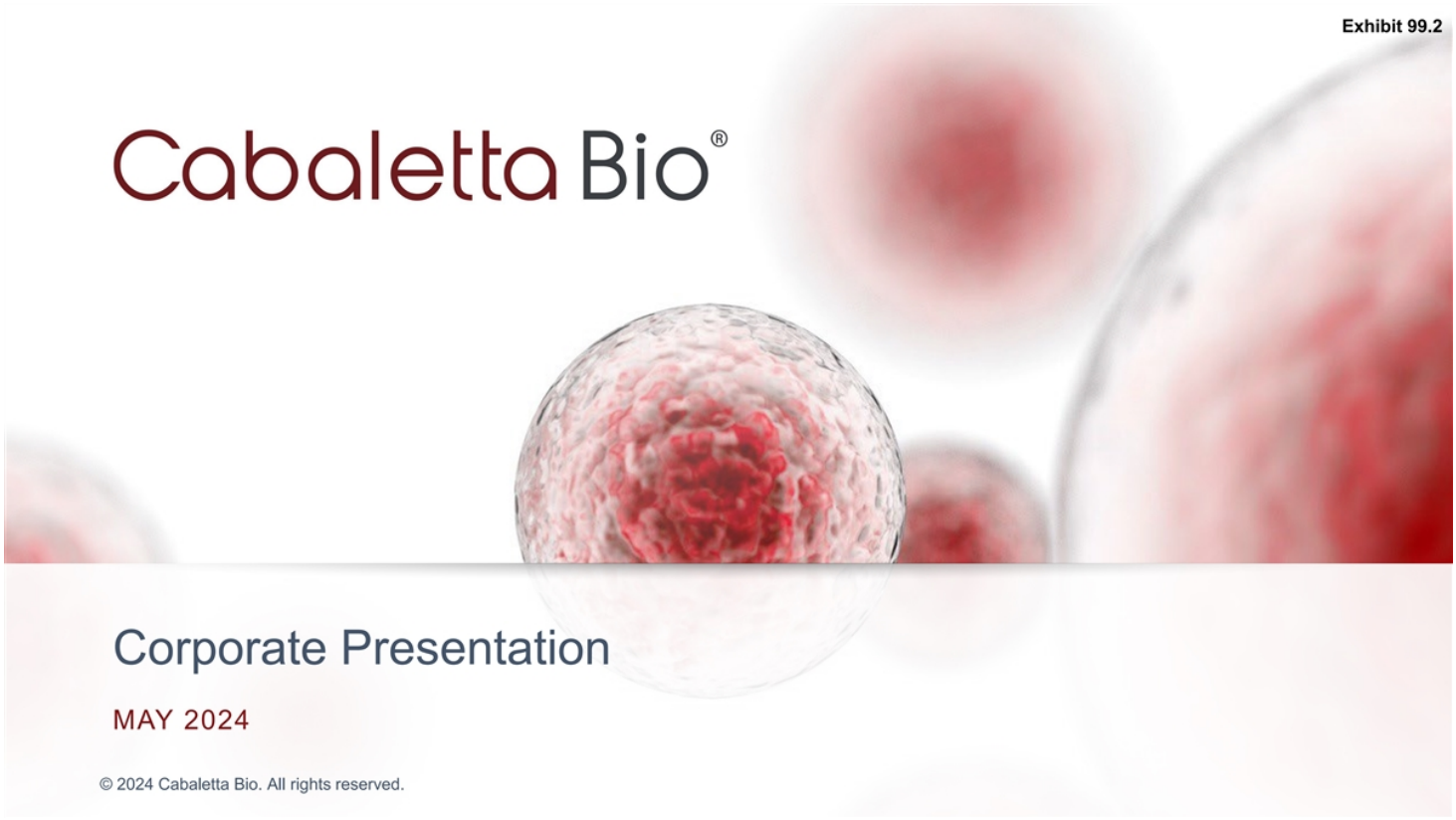
Chief Financial Officer
investors@cabalettabio.com

William Gramig
Stern Investor Relations, Inc.
william.gramig@sternir.com

Exhibit 99.2

Cabaletta Bio®



Corporate Presentation

MAY 2024

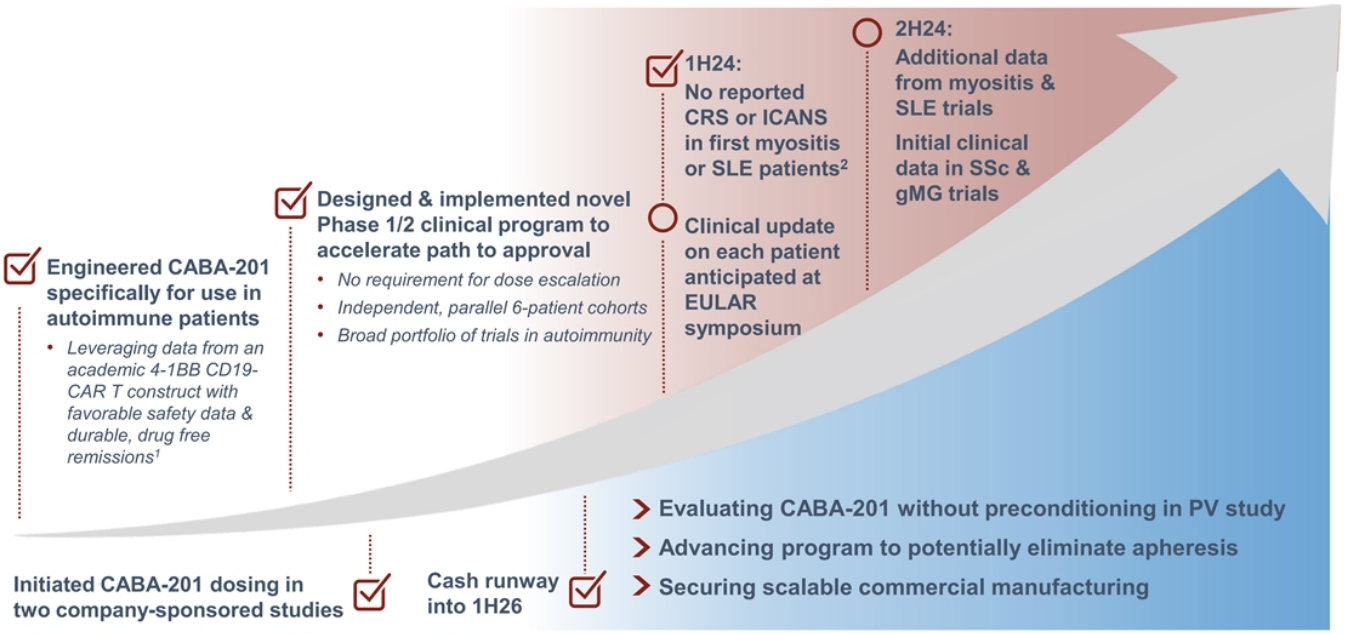
Disclaimer

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, clinical trial design, 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 planned initial clinical data read-out in the first half of 2024 at the EULAR 2024 symposium for patients with myositis and SLE treated with CABA-201; our planned initial clinical data read-out in the second half of 2024 for patients with SSc and gMG treated with CABA-201; 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 DesCAARTes™ Phase 1 trial, including the significance and impact around reported safety and clinical and translational data of cohorts from our DesCAARTes™ and MusCAARTes™ Phase 1 trials; 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; 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 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, DSG3-CAART 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, our plans to evaluate additional cohorts in the DesCAARTes™ trial, including a cohort implementing a pre-treatment regimen, 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 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

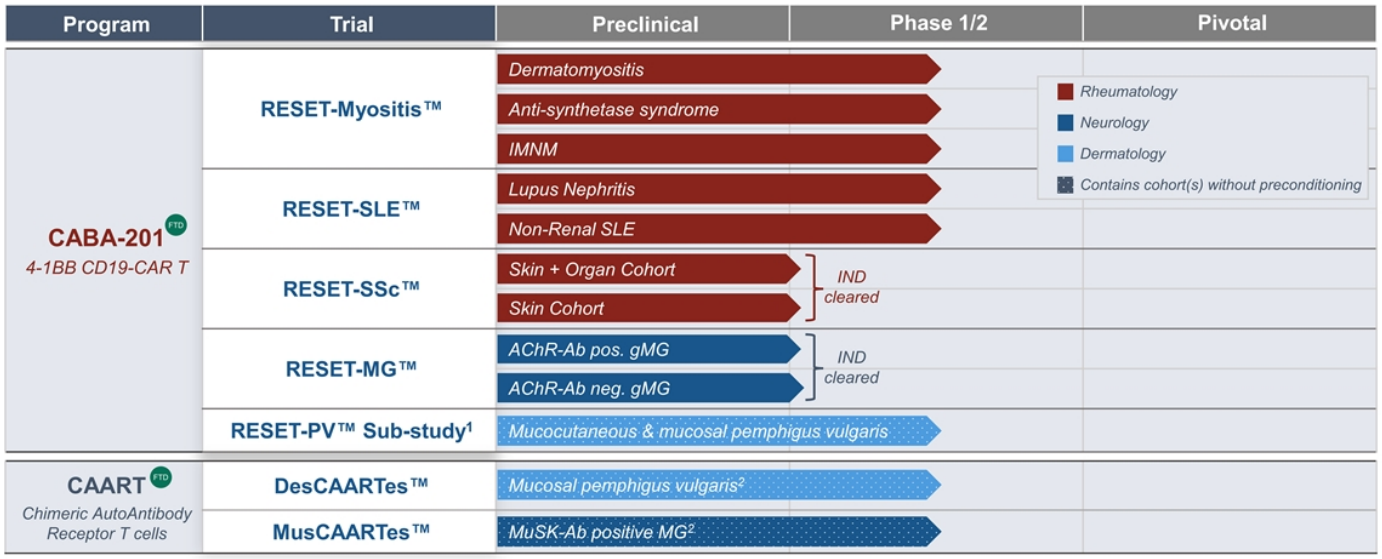


SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis

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. Within the 28-day dose limiting toxicity observation window for each patient.

Pipeline targeting autoimmune diseases with high unmet need

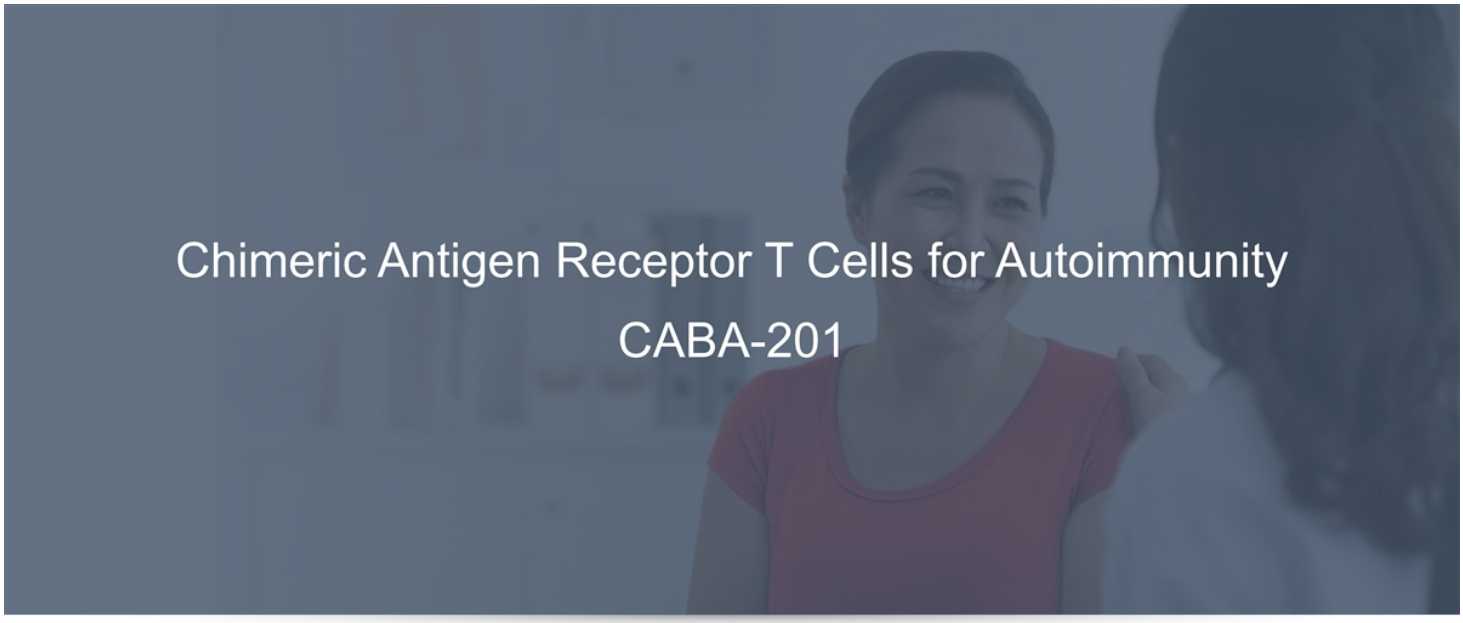
Innovative and scalable clinical strategy with potential for accelerated development path



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 and not currently dosing patients with DSG3-CAART or MuSK-CAART.

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



Cabaletta Bio®

Academic data: Immune system reset in autoimmune patients

Promising clinical responses in 15 patients across several autoimmune diseases with 4-1BB CD19-CAR T[1,2]

100%
Objective clinical response rate in SLE, myositis, SSc

T cell expansion & B cell depletion within 1st month enabled robust clinical improvement by 3 months

<7%
Rate of CRS more severe than fever (1/15)

11/15 patients reported by Erlangen group with CRS, 10/11 with fever*

Single grade 1 ICANS event reported (transient dizziness)

**One grade 2 CRS (increased oxygen requirement in patient with pre-existing lung disease[3])*

2+
Years of SLE durable drug-free remission

Up to 29 months of follow-up in the 15 patients reported by Erlangen group

3-7
Months to naïve B cell repopulation

In patients with ≥5 months of follow-up, complete B cell elimination followed by return of healthy naïve B cells within median of ~3 months

One IIM subject reported to have recurrence of muscle disease ~12 months after CD19-CAR T administration; BCMA-CAR T therapy planned

CRS – Cytokine release syndrome; ICANS – Immune effector cell-associated neurotoxicity syndrome

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.
2. The construct utilized in these studies has a similar design to CABA-201, sharing the 4-1BB costimulatory domain, but is a different construct.
3. Taubmann J, et al. Efficacy and Safety of CAR-T-Cell Treatment in Refractory Antisynthetase Syndrome – Data of the First Three Patients [ACR abstract; Nov 14, 2023].

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

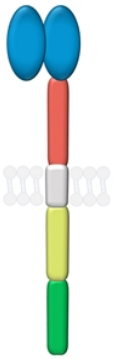
Cabaletta's CD19 binder with similar *in vitro* & *in vivo* activity to FMC63[1,2] (binder used in academic report[3])

No CRS or ICANS reported in either of the first myositis or SLE patients

Fully human anti-CD19 binder
Similar binding affinity & biologic activity to FMC63, with binding to the same epitope[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.

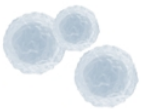
CABA-201

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

Phase 1/2 Trials — Preclinical

Rheum
Neuro
Undiscl.

Myositis	SLE	SSc	gMG	2024
				
♀>♂	♀>♂	♀>♂	♀>♂	
Typical onset middle age Only FDA-approved therapy is IVIg in DM High mortality due to lung & cardiac involvement	Affects young women & people of color ~40% with lupus nephritis, which carries ~25% risk of death or ESRD within 10y	Middle age onset common Progressive skin & organ fibrosis with lung, cardiac, renal damage Average survival of 12y	Bimodal age of onset Profound weakness that can be disabling Risk for myasthenic crises, with respiratory failure	Autoimmune diseases in which B cells play a key role
U.S. Prevalence				
~66k	**~160-320k**	**~88k**	**~55k**	**Over 1 million**

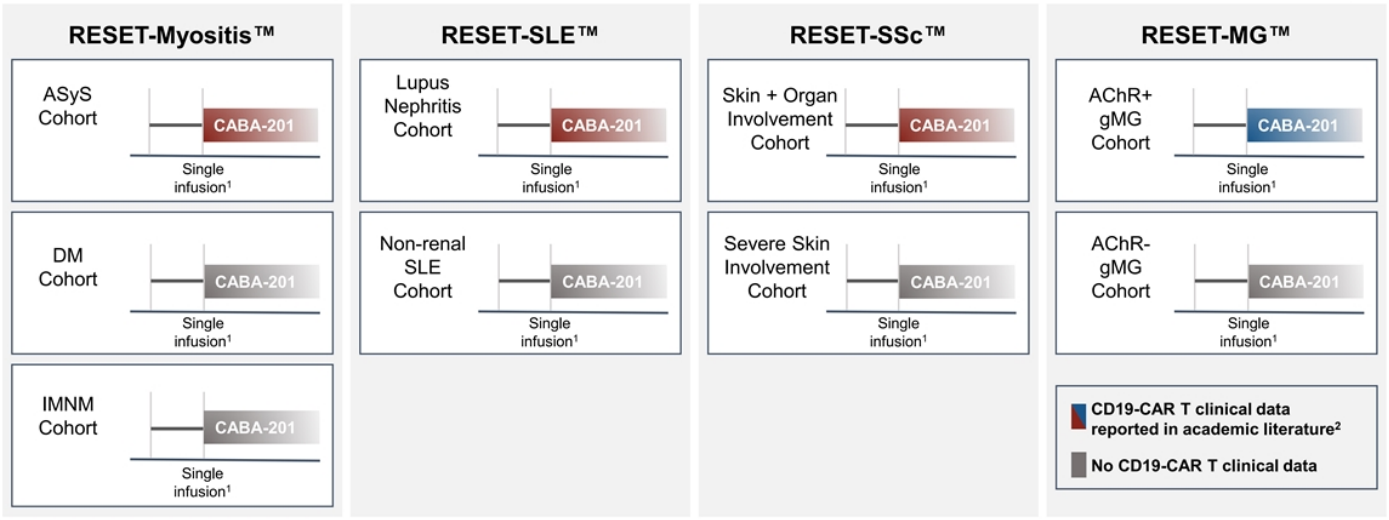
CABA-201 also to be evaluated in the absence of preconditioning in pemphigus vulgaris sub-study

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

Patient dosing commenced; enrolling patients with active myositis with DM, ASyS or IMNM subtypes

Screening

Key inclusion criteria

- Adults 18-65y
- Clinical IIM diagnosis
- Subtype based on serology
- Disease activity despite standard of care
- Recommended vaccines

Key exclusion criteria

- Cancer associated myositis
- Significant lung or cardiac impairment
- Treatment with anti-B cell agent within prior ~6 months
- Treatment with biologic agent within prior ~3 months

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

- **Pharmacokinetics / pharmacodynamics**
- **Myositis serology**
- **Myositis clinical activity – Total Improvement Score**
- **Functional & radiographic evidence of disease**

IIM – Idiopathic inflammatory myopathy; DM – Dermatomyositis; ASyS – Anti-synthetase syndrome; 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. 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

Patient dosing commenced; enrolling patients with active SLE with or without renal involvement

Screening

Key inclusion criteria

- Adults 18-65y
- Clinical SLE diagnosis
- Confirmatory serology
- Disease activity despite standard of care
- Recommended vaccines

Key exclusion criteria

- Treatment with anti-B cell agent within prior ~6 months
- Treatment with biologic agent within prior ~3 months

Phase 1/2 Study Design

Open-label trial with parallel 6-subject cohorts

SLE with lupus nephritis → **CABA-201** *Single dose of 1x10^6 cells/kg[1]*

SLE without renal disease → **CABA-201** *Single dose of 1x10^6 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

- **Pharmacokinetics / pharmacodynamics**
- **SLE serology**
- **SLE clinical activity**

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

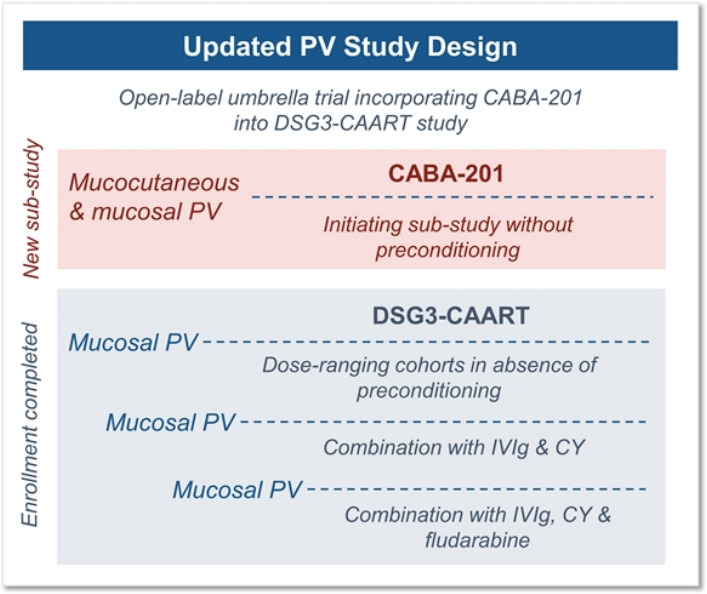
Evaluating CABA-201 without preconditioning in pemphigus

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

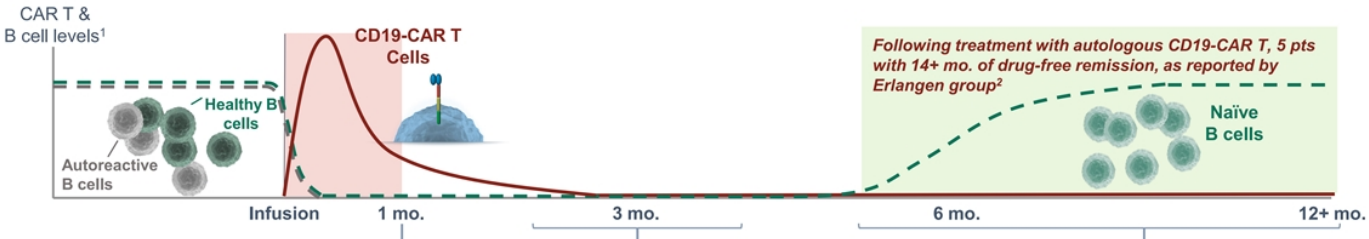


DSG – Desmoglein; PV – Pemphigus vulgaris

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

For CABA-201, translational measures in 1st month may inform clinical outcomes at 3 months



Metrics of evaluation	Within 1 month	~3 months	5-12+ 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 ❑ 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
Patient experience	❑ Hospitalization requirements ❑ Apheresis & preconditioning ❑ Single vs. multiple infusions	❑ Chronic maintenance therapy / concomitant medications, if any	❑ Chronic maintenance / concomitant medications, if any

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

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.

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**
  - **Opportunities for automated manufacturing**
  - **Cabaletta-operated facility**
  - **Strategic partnership(s)**
- **Continuous focus on innovations to address scale**
  - **Internal program**
  - **Cellares technology assessment program ongoing**

Securing & expanding our leadership in autoimmune cell therapy

Rapidly advancing to address patient need

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
- Optimizing the preconditioning regimen
- 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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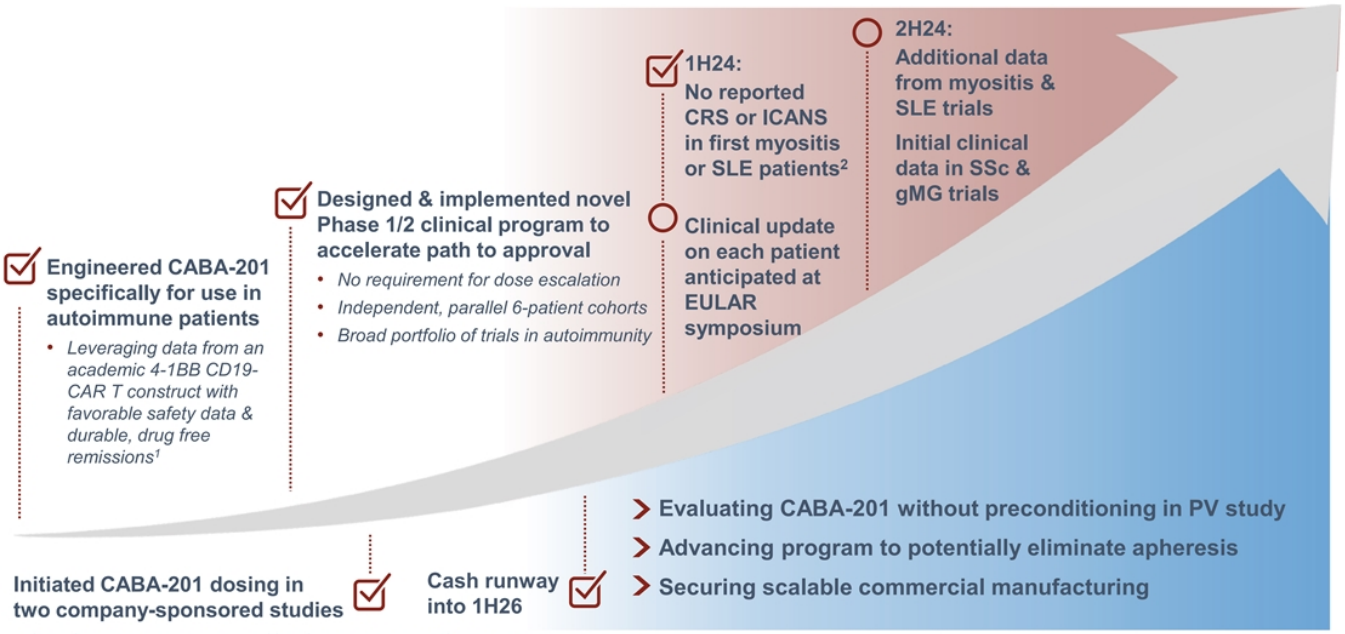
Realizing the vision to transform autoimmune disease treatment



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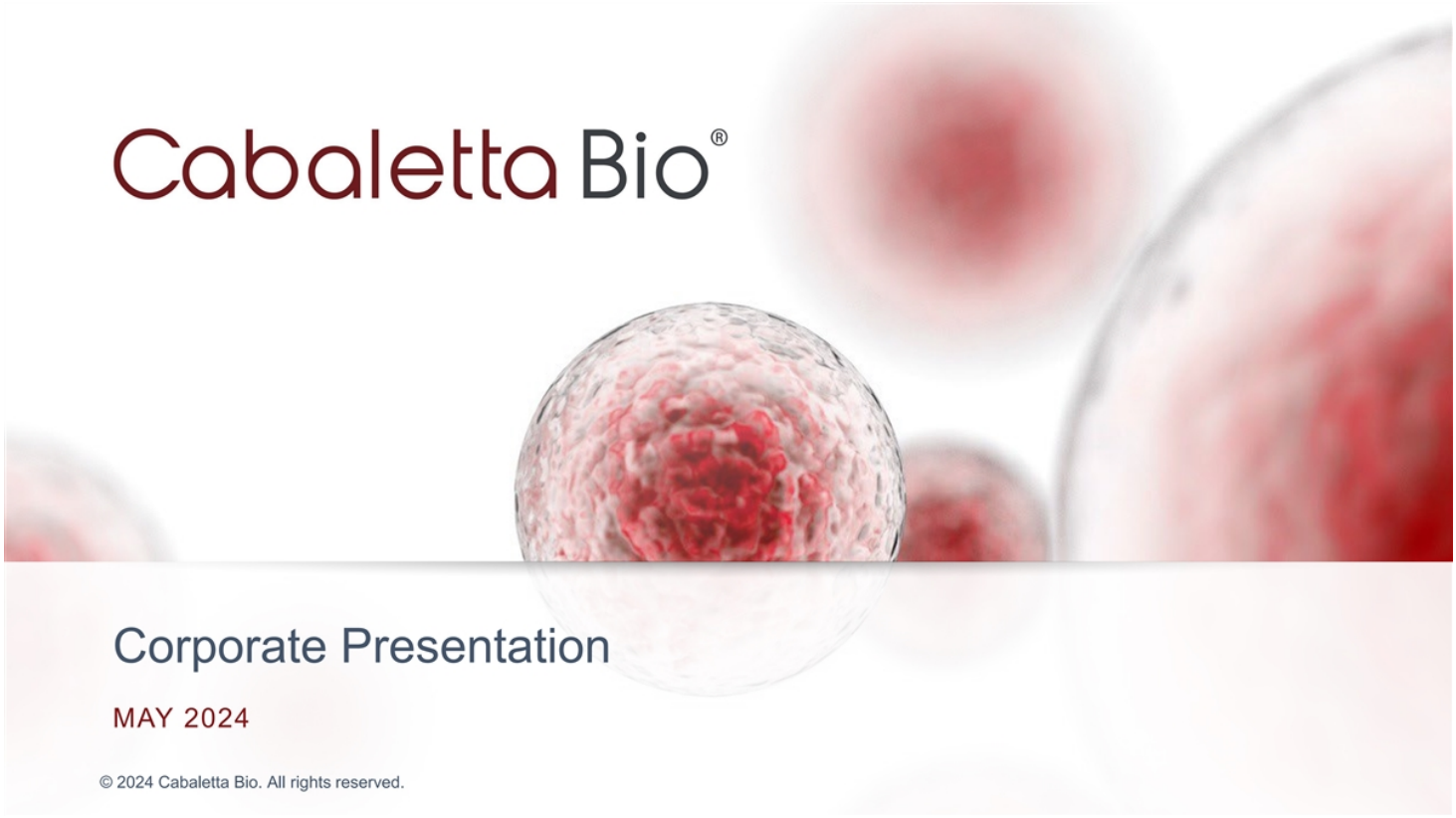
2. Within the 28-day dose limiting toxicity observation window for each patient.

Cabaletta Bio®



Corporate Presentation

MAY 2024