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

January 13, 2025
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 January 13, 2025, Cabaletta Bio, Inc. ("Cabaletta" or the "Company") disclosed that its unaudited cash and cash equivalents as of December 31, 2024 was $164 million. The Company expects that this cash position as of December 31, 2024, will enable it to fund its updated operating plan, including recently accelerated clinical assumptions, into the first half of 2026.

The information contained in Item 2.02 of this Form 8-K is unaudited and preliminary and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2024. The audit of the Company's consolidated financial statements for the year ended December 31, 2024 is ongoing and could result in changes to the information set forth above.

The information contained in Item 2.02 of this Current Report on Form 8-K 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 January 13, 2025, 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 furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

On January 13, 2025, the Company also issued a Press Release announcing its recent pipeline and operational progress and outlining its strategic priorities and anticipated key milestones for 2025 (the "Press Release"). A copy of the Press Release is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 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 8.01 Other Events.

On January 13, 2025, the Company issued the Press Release announcing its recent pipeline and operational progress and outlining its strategic priorities and anticipated key milestones for 2025.

Recent Pipeline and Operational Progress

- As of December 31, 2024, 21 patients have been enrolled across 44 actively recruiting clinical sites in the U.S. and Europe across the RESET clinical development program.
- In the first 10 patients dosed with rese-cel with at least one month of follow-up, 90% have experienced either no cytokine release syndrome (CRS) or grade 1 (fever) CRS and 90% have experienced no immune effector cell-associated neurotoxicity syndrome (ICANS). Data from these patients will be presented at an upcoming scientific meeting in February 2025.
- Today, Cabaletta announced the following progress in support of its commitment to advance innovations that improve the patient and physician experience, in addition to broadening the potential of rese-cel for patients:
    - The first patient has been enrolled in the RESET-PV trial, evaluating rese-cel without preconditioning in patients with pemphigus vulgaris.

- The first juvenile myositis clinical site in the RESET-Myositis trial is now open and actively recruiting. The U.S. Food and Drug Administration (FDA) previously granted Rare Pediatric Disease designation for rese-cel in juvenile dermatomyositis.
- The first patient has been enrolled in the RESET-MG™ trial, evaluating rese-cel in patients with myasthenia gravis.
- The Investigational New Drug (IND) application for rese-cel has been allowed to proceed within the routine 30-day window by the FDA for the RESET-MS trial, a Phase 1/2 study evaluating rese-cel in patients with multiple sclerosis (MS). In addition, the FDA has granted Fast Track Designation to rese-cel for the treatment of relapsing and progressive forms of MS.

- In order to expand our clinical supply to address the increasing pace of enrollment in our clinical trials as well as to prepare for registrational trial(s) across the RESET clinical development program while expanding our manufacturing options for rese-cel, Cabaletta has expanded its CDMO agreement with Lonza, a leading Contract Development and Manufacturing Organization (CDMO), to supply rese-cel clinical product under current Good Manufacturing Practices as soon as the second half of 2025.
- In November 2024, Cabaletta presented new and updated clinical data on rese-cel supporting its potential to achieve drug-free, compelling clinical responses based on eight patients dosed across the ongoing Phase 1/2 RESET-Myositis, RESET-SLE™ and RESET-SSc™ clinical trials at the American College of Rheumatology (ACR) Convergence 2024 conference.

Strategic Priorities and Anticipated Key Milestones for 2025

Gain alignment with the FDA on a path to registration for rese-cel that leverages our indication-specific trials to rapidly advance registrational programs

- The Company now plans to meet with the FDA regarding registrational trial designs for rese-cel in the first half of 2025 based on the emerging clinical and translational data and increased pace of enrollment.

Enroll patients and complete dosing in multiple disease-specific cohorts across the RESET clinical development program

- Present new and updated clinical and translational data on rese-cel throughout 2025.

Continue advancing innovations designed to expand patient access and provide streamlined and positive experiences with rese-cel for patients and providers

- **Evaluate rese-cel with no preconditioning:** Generate clinical and translational data evaluating rese-cel without preconditioning from the RESET-PV trial in 2025.
- **Align with FDA on whole blood replacement for apheresis:** Continue to advance the whole blood manufacturing program as a potential replacement for apheresis and seek to align with FDA on a strategy to incorporate it into the RESET clinical development program.

Financial Guidance

Cabaletta ended the fourth quarter of 2024 with unaudited cash and cash equivalents of $164 million. The Company expects that this cash position as of December 31, 2024 will enable it to fund its updated operating plan, including recently accelerated clinical assumptions, into the first half of 2026.

About the RESET-MS™ Trial

The RESET-MS™ trial is a Phase 1/2 open-label, dose escalation study of rese-cel in subjects with relapsing and progressive forms of multiple sclerosis (MS), evaluated in separate cohorts. Subjects will receive a one-time infusion of rese-cel following a preconditioning regimen of fludarabine and cyclophosphamide. Key inclusion criteria for the relapsing MS cohort include patients between ages 18 to 60 (inclusive), evidence of clinical relapse during the previous 2 years, and prior treatment with a high efficacy therapy for at least 6 months. Key progressive MS inclusion criteria include patients between ages 18 to 60 (inclusive) and evidence of objective disease worsening during the prior year while on standard of care therapy for at least 6 months. Key exclusion criteria for both cohorts include history of fulminant MS within 5 years, a prior history of seizures or other clinically significant concomitant CNS pathology, history of progressive multifocal leukoencephalopathy, as well as treatment with a B cell depleting agent within the prior approximately 20 weeks.

About rese-cel (formerly referred to as CABA-201)

Rese-cel is a 4-1BB-containing fully human CD19-CAR T cell investigational therapy for patients with autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease. Following a one-time infusion of a weight-based dose, rese-cel is designed to transiently and completely deplete all CD19-positive cells. This approach has the potential to reset the immune system and result in compelling clinical responses without chronic therapy requirements in patients. Cabaletta is currently evaluating rese-cel in the RESET™ (REstoring SElf-Tolerance) clinical development program which includes multiple disease-specific, company-sponsored clinical trials across growing portfolios of autoimmune diseases in a broad range of therapeutic areas, including rheumatology, neurology and dermatology.

Forward-Looking Statements

The information under this Item 8.01 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 business plans and objectives as a whole; Cabaletta's ability to realize its vision of launching the first curative targeted cell therapy designed specifically 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, including the timing and results of Cabaletta's clinical trials and its ability to conduct and complete clinical trials; expectation that clinical results will support rese-cel's safety and activity profile; statements regarding the timing of interactions with regulatory authorities, including such authorities' review of safety information from Cabaletta's ongoing clinical trials and potential registrational pathway for rese-cel; Cabaletta's expectations around the potential success and therapeutic benefits of rese-cel, including its belief that rese-cel has the potential to reset the immune system and result in compelling clinical responses without chronic therapy requirements in patients; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel in patients with SLE, myositis, SSc and gMG and advancement of the RESET-PV and RESET-MS trials, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; the clinical significance of the clinical data read-out at upcoming scientific meetings; Cabaletta's ability to expand its clinical supply for registrational trial(s) across the RESET clinical development program as well as to expand its manufacturing options for rese-cel; Cabaletta's ability to increase enrollment in its US and Europe clinical networks; Cabaletta's ability to leverage its growing clinical trial network to accelerate development of its therapy for patients and to generate clinical and translational data; Cabaletta's advancement of the whole blood manufacturing program as a potential replacement for apheresis, as well as its potential alignment with FDA in connection thereto; and Cabaletta's use of capital, expense and other financial results in the future and its ability to fund operations into the first half of 2026.

Any forward-looking statements in this Item 8.01 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 rese-cel; 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 rese-cel; 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; 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 subsequent filings with the Securities and Exchange Commission. All information in this Item 8.01 is as of the date of this Current Report on Form 8-K, and the Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Corporate Presentation, dated January 13, 2025, furnished herewith.
99.2	Press Release issued by the registrant on January 13, 2025, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

SIGNATURE

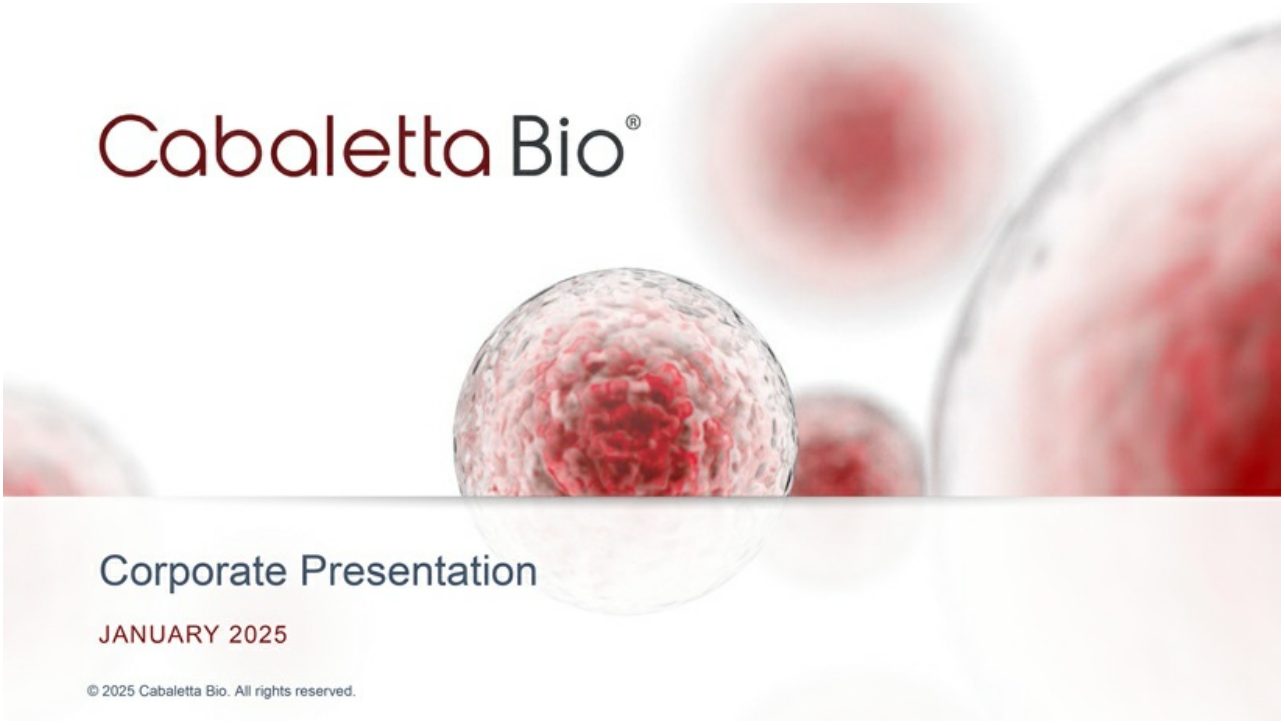
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CABALETTA BIO, INC.

Date: January 13, 2025

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

Exhibit 99.1



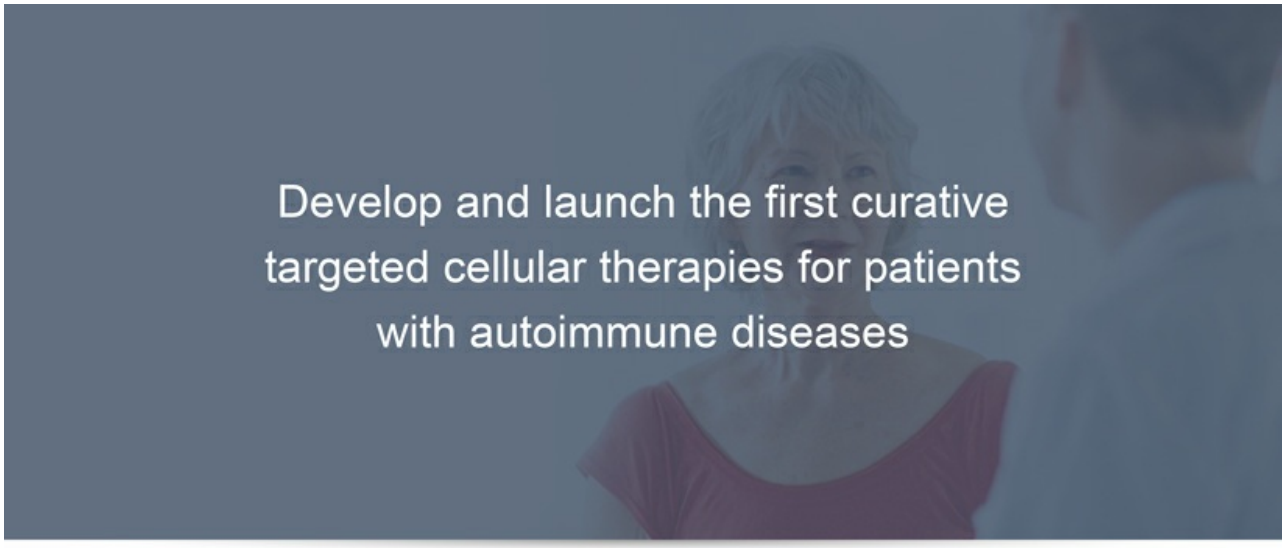
Corporate Presentation

JANUARY 2025

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 technology; 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 rese-cel in patients with autoimmune diseases; the Company's business plans and objectives; our expectations around the potential success and therapeutic and clinical benefits of rese-cel and our other product candidates, as well as our ability to successfully complete research and further development and commercialization of our drug candidates in current or future indications, including the timing and results of our clinical trials and our ability to conduct and complete clinical trials; expectation that clinical results will support rese-cel's safety and activity profile; our plan to leverage increasing clinical data and a unique development program for rese-cel; the clinical significance of the clinical data read-out at upcoming medical or scientific meetings; our belief that rese-cel may enable achieving drug-free, durable meaningful clinical responses, through an immune reset; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel in patients with SLE, myositis, SSc and gMG and advancement of the RESET-PV and RESET-MS trials, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; our 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 rese-cel; the timing any planned regulatory filings for our development programs, including IND applications; the progress and results of our MusCAARTes™ Phase 1 trial, and impact around reported safety and clinical and translational data of cohorts from our MusCAARTes™ Phase 1 trial; Cabaletta's advancement of the whole blood manufacturing program as a potential replacement for apheresis, as well as its potential alignment with FDA in connection thereto; expectation that clinical results will support rese-cel'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 and potential registrational pathway for rese-cel; 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 increase enrollment from our rapidly expanding clinical network in the RESET clinical trial program in the US and Europe; 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 Fast Track Designations for our product candidates; 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 our manufacturing strategy to enable expansion of clinical supply and efficiently scale commercial supply for rese-cel; our potential commercial opportunities, including value and addressable market, for our product candidates. 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 rese-cel 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 rese-cel, 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 rese-cel; 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®

2025: Realizing our vision by defining an efficient path to approval

Planning to leverage increasing clinical data and unique development program for rese-cel (resecabtagene autoleucel; CABA-201)

Compelling clinical efficacy with favorable safety profile & rapidly growing enrollment

- **Compelling clinical efficacy** data in active, refractory autoimmune patients[1]
- **Favorable safety profile** in first 10 patients dosed, 90% experienced either no CRS or grade 1 (fever) CRS and 90% experienced no ICANS
- **Immunosuppressant-free outcomes** observed with patients discontinuing all immunosuppressants from rese-cel infusion through follow up period[1]

Unique development strategy designed to accelerate time to approval and launch

- **Multiple disease-specific cohorts** with a common design allow for a potentially accelerated path to approval with broad evaluation of autoimmune indications
- **One weight-based dose** administered as a **single infusion**; dose supported by clinical & translational data[1]
- **Industry-leading clinical network** with 44 active clinical sites and growing in the US and Europe[2]

Multiple near-term catalysts including clarity on potential path to approval

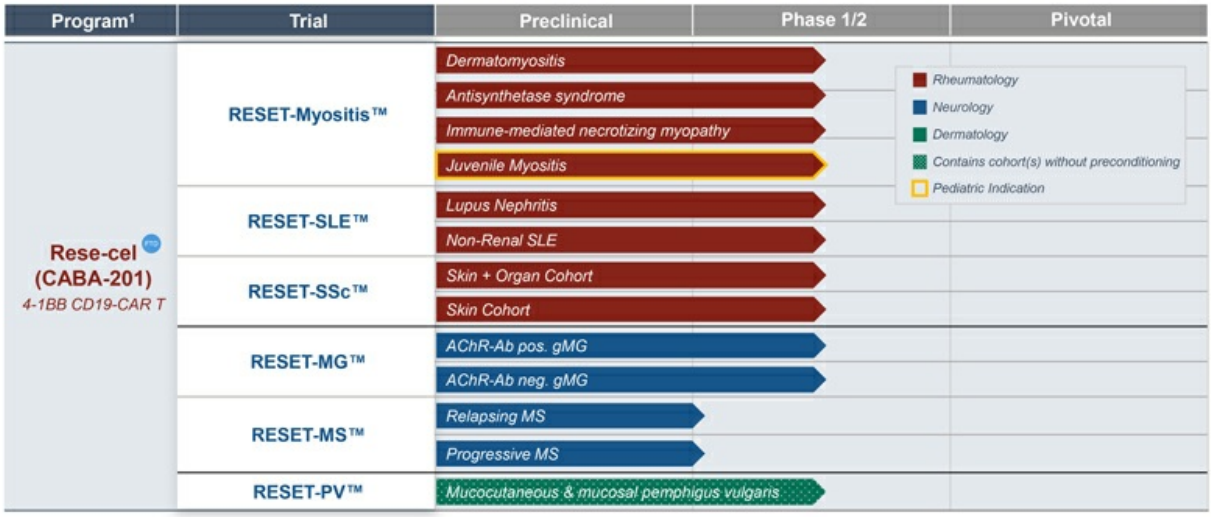
- **Plan to meet with FDA to align on registrational trial design in 1H25**
- **Enroll and complete dosing** in multiple disease-specific cohorts in 2025
- **Present clinical data** on rese-cel at medical meetings throughout 2025, including data evaluating rese-cel without preconditioning

Patients are seeking a drug-free, symptom-free life which is rarely achieved despite current therapies; physicians also prioritize prevention of end-organ damage[3]

1. Abstract 1733: Safety and efficacy of CABA-201, a fully human, autologous 4-1BB anti-CD19 CAR T cell therapy in patients with immune-mediated necrotizing myopathy and systemic lupus erythematosus from the RESET-Myositis™ and RESET-SLE™ clinical trials. ACR Convergence 2024.
2. Clinicaltrials.gov as of December 31, 2024
3. Golder, et al. Lupus. 2018;27(3): 501-506

Innovative clinical strategy with potential for accelerated regulatory path

RESET clinical program has disease-specific cohorts designed to evolve directly into registrational studies



RESET™ – **RE**storing **SE**lf-Tolerance; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis; MS – Multiple sclerosis; SLE – Systemic lupus erythematosus

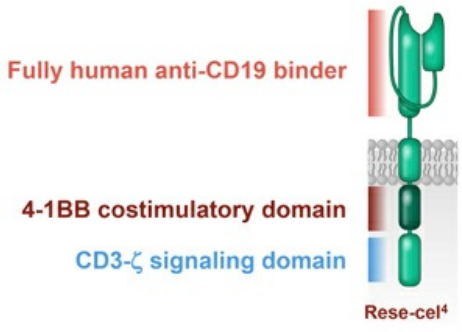
1. Additional pipeline candidate includes MuSK-CAART for MuSK-Ab positive MG, currently being evaluated in a Phase 1 trial.

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

Cabaletta Bio®

Rese-cel: CD19-CAR T specifically designed for autoimmunity

Cabaletta rese-cel binder with similar *in vitro* & *in vivo* activity to construct used in academic studies[1,3]



Rese-cel product design & clinical / translational data

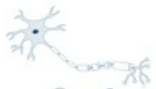
- **4-1BB costimulatory domain with fully human binder**
  - **Binder with similar affinity & biologic activity to academic FMC63 binder while binding to the same epitopes[1,2]**
- **Same weight-based dose as in academic studies**
  - **Potential to provide immune reset based on initial clinical and translational data[5]**
- **Initial patients treated with rese-cel have shown compelling clinical responses with safety data that supports autoimmune development[6]**

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. Transmembrane domain in rese-cel 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.
5. Volkov, Jenell, et al. "Case study of CD19 CAR T therapy in a subject with immune-mediate necrotizing myopathy treated in the RESET-Myositis phase I/II trial." Molecular Therapy 32.11 (2024): 3821-3828.
6. Abstract 1733: Safety and Efficacy of CABA-201, a Fully Human, Autologous 4-1BB Anti-CD19 CAR T Cell Therapy in Patients with Immune-Mediated Necrotizing Myopathy and Systemic Lupus Erythematosus from the RESET-Myositis™ and RESET-SLE™ Clinical Trials. ACR 2024.

RESET™ program addressing several autoimmune markets

Broad portfolio with six RESET trials designed to address high unmet need and realize the potential of rese-cel

Phase 1/2 Trials — No Flu/Cy

Myositis	SLE	SSc	gMG	MS	PV
					
♀>♂	♀>♂	♀>♂	♀>♂	♀>♂	
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	Chronic inflammation, axon loss, cognitive impairment, and irreversible neurologic damage	Pure autoantibody & B-cell mediated autoimmune disease Characterized by painful blisters & erosions
U.S. Prevalence					
~68k	~160-320k	~88k	~55k	~750k	~13k
EU Prevalence					
~85k	~150k	~60k	~100k	~550k	~21k

Rheum *Neuro* *Derm*

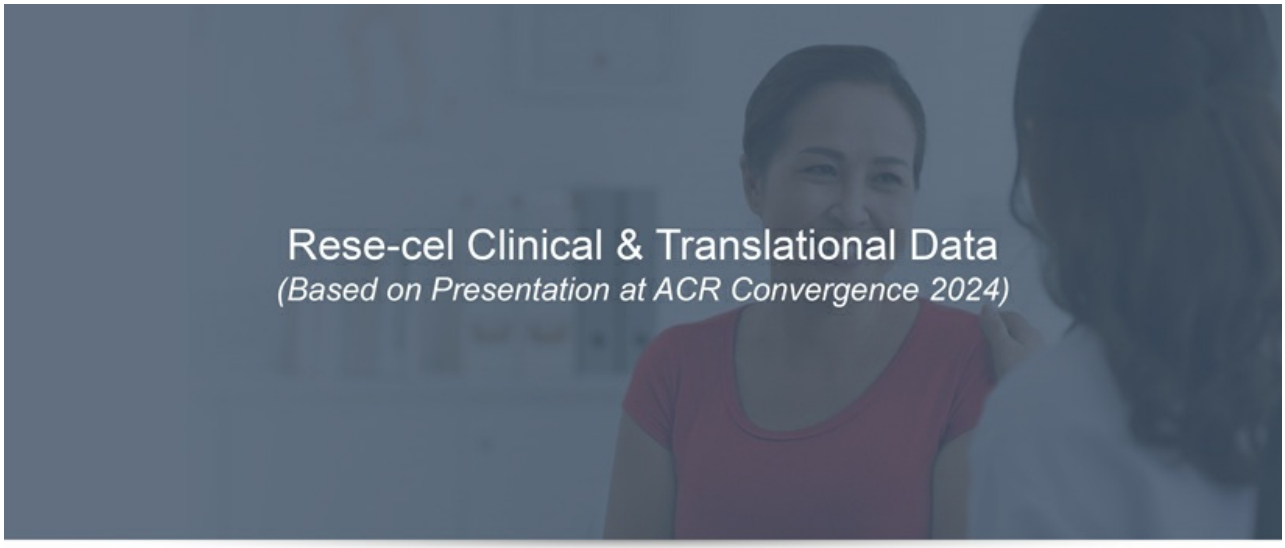
SLE – Systemic lupus erythematosus; DM – Dermatomyositis; SSc – Systemic sclerosis; gMG – Generalized myasthenia gravis; MS – multiple sclerosis; ESRD – End-stage renal disease; PV – pemphigus vulgaris

Industry-leading clinical site footprint across RESET™ program[1]

SLE sites | Myositis sites | Juvenile myositis sites | SSc sites | MG sites | PV sites

21 patients enrolled[2] across the RESET™ studies, with 44 actively recruiting clinical sites in the US & Europe

1. Data per clinicaltrials.gov as of December 31, 2024, as compared to companies with actively recruiting U.S. clinical sites for autoimmune cell therapy trials under company-sponsored INDs.
2. As of December 31, 2024.



Cabaletta Bio®

Key inclusion and exclusion criteria in RESET™ clinical program

Designed to evaluate the safety and tolerability of rese-cel in subjects with active, refractory disease

Key inclusion criteria[1–3]

Evidence of active disease despite prior or current treatment with standard of care

RESET-Myositis™	RESET-SLE™	RESET-SSc™
• Age ≥18 and ≤75 with a diagnosis of IIM (ASyS, DM, or IMNM) • Presence of at least one myositis antibody • **JIIM**: Age ≥6 and ≤17 with presence of at least one MSA or MAA	• Age ≥18 and ≤65 with an SLE diagnosis • Positive ANA or anti-dsDNA at screening • **SLE (non-renal)**: active, moderate to severe SLE, SLEDAI-2K ≥8; pure class V LN patients eligible for this cohort • **LN**: active, biopsy-proven LN class III or IV (± class V)	• Age ≥18 and ≤70 with a limited or diffuse SSc diagnosis • Evidence of significant skin, pulmonary, renal, or cardiac involvement

Key exclusion criteria[1–3]

B cell-depleting agent within prior 3-6 months; Previous CAR T therapy and/or HSCT

• Cancer-associated myositis • Significant lung or cardiac impairment	• Presence of kidney disease other than LN • Current symptoms of severe, progressive, or uncontrolled pulmonary or cardiac disease	• Severe lung or cardiac impairment

Anticipate enrolling and completing dosing in multiple disease-specific cohorts in 2025; similarly designed RESET-MG™ Phase 1/2 trial enrolling

ASyS, antisynthetase syndrome; CAR, chimeric antigen receptor; DM, dermatomyositis; HSCT, hematopoietic stem cell transplantation; IIM, idiopathic inflammatory myopathy; JIIM, juvenile idiopathic inflammatory myopathy; LN, lupus nephritis; MAA, myositis-associated antibody; SLEDAI-2k, SLE disease activity index 2000; SSc, systemic sclerosis.

1. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06121297 (accessed October 2024).
2. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06328777 (accessed October 2024).
3. ClinicalTrials.gov. Available at: www.clinicaltrials.gov/study/NCT06154252 (accessed October 2024).

Baseline characteristics of first 8 patients in the RESET™ program

All patients had active, refractory disease and most had failed B cell-targeting therapies

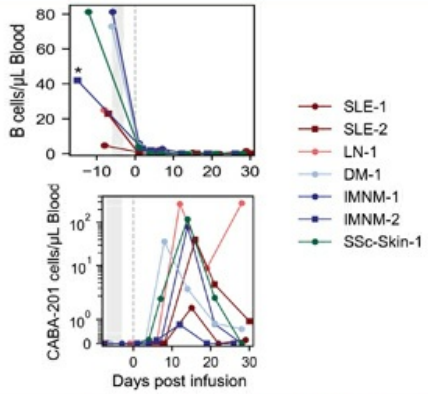
	RESET-Myositis™			RESET-SLE™				RESET-SSc™
Patient / Cohort	**IMNM-1**	**IMNM-2**	**DM-1**	**SLE-1**† Class V LN	**SLE-2**	**SLE-3**	**LN-1**	**SSc-Skin-1** (severe skin cohort)
Age, sex	33 M	60 M	57 M	26 M	36 F	44 F	24 F	66 F
Disease duration	~2 years	~4 years	~4 years	~6 years	~17 years	~9 years	~2 years	~2 years
Autoantibodies	SRP	HMGCR	SAE	dsDNA	dsDNA	dsDNA	dsDNA	RNA P III
Baseline Disease activity*	**MMT-8**			**SLEDAI-2K**				**mRSS**
	130	126	131	26	10	8	22	42
	CK (U/L)			**UPCR (mg/mg)**				
	617	4725	94	1.08†	n/a	n/a	7.22	
Therapies at Screening	GC, MTX	GC, IVIG	GC, MMF, HCQ	GC, MMF, HCQ	GC, AZA, HCQ	HCQ, MMF, BEL	GC, ANI, VOC, MMF, HCQ	MMF
Other prior therapies	RTX, IVIG	RTX, MMF, MTX	IVIG	CYC, BEL, VOC, TAC	MSC, RTX, ANI, BEL, ADA, MTX	GC, MTX	BEL, LEF	HCQ
GC dose at Screening (mg/day)	5	5	20	10	7	n/a	20	n/a

*Baseline disease activity = activity before pre-conditioning. † SLE-1 had class V LN; inclusion criteria for LN cohort requires class III/IV LN.
ADA, adalimumab; ANI, anifrolumab; AZA, azathioprine; BEL, belimumab; CK, creatinine kinase; dsDNA, double-stranded DNA; GC, glucocorticoid; HCQ, hydroxychloroquine; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IVIG, intravenous immunoglobulin; LEF, leflunomide; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; mRSS, modified Rodnan skin score; MSC, mesenchymal stem cell; MTX, methotrexate; RNA P III, RNA polymerase III; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SRP, signal recognition particle; TAC, tacrolimus; U/L, units per liter; UPCR, urinary protein-to-creatinine ratio; VOC, voclosporin.
Cabaletta Bio: Data on file.

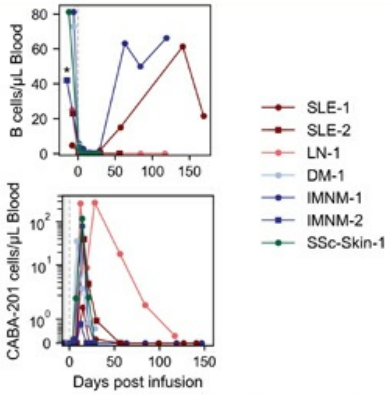
Consistent and deep B cell depletion by Day 22[1]

In patients with >3-month follow-up, B cell repopulation with naïve cells started as early as 8 weeks

1st 30 days: B cell depletion & rese-cel expansion



1st 150 days: B cell depletion / repopulation & rese-cel expansion



Rese-cel exhibited a PK/PD profile with peak expansion between Day 8 and 15 as expected, with a later 2nd peak for the first LN patient, suggestive of a possible occult infection[1]

PK, pharmacokinetic; PD, pharmacodynamic
* Pre-infusion B-cell levels were measured at pre-preconditioning for all subjects other than IMNM-2 where apheresis was used
1. Nunez et al. Correlative Studies of CABA-201 from the RESET-Myositis™ and RESET-SLE™ Clinical Trials. Presented at ACR Convergence 2024. Abstract 0324

Incidence and severity of adverse events in the first 8 patients*

	RESET-Myositis™			RESET-SLE™				RESET-SSc™
Cohort	**IMNM**		**DM**	**Non-renal SLE**			**LN**	**SSc – Severe Skin**
Patient	**IMNM-1**	**IMNM-2**	**DM-1**	**SLE-1**	**SLE-2**	**SLE-3**	**LN-1****	**SSc-Skin-1**
CRS†	None	None	None	None	Grade 1	None	Grade 1	Grade 2
ICANS†	None	None	None	None	None	None	Grade 4*	None
Serious infections‡	None	None	None	None	None	None	None	None
Hypogammaglobulinemia	None	None	None	None	None	None	Grade 2	None
Related SAEs (Grade)§ (excluding CRS and ICANS)	None	None	None	None	None	None	Fever (1) Pancytopenia¶ (4)	None

***Prior to infusion[1], LN-1 patient experienced acute, febrile inflammatory events & highly elevated pro-inflammatory cytokines that continued after treatment, suggesting a possible occult infection; supportive data from TCR clonal sequencing[2]. ICANS event resolved completely with standard therapies.*

*As of Nov 1, 2024; Primary endpoint is incidence and severity of Adverse Events through Day 29. †Graded per ASTCT Consensus Grading Criteria. Of these patients, only DM-1, SLE-2, SLE-3, and SSc-Skin-1 received medication for seizure prophylaxis. Tocilizumab was not administered for any cases of CRS. ‡Coded in System Organ Class of Infections and Infestations and meets seriousness criteria. §As assessed per FDA guidelines.

¶Consistent with "Prolonged Cytopenias," which is a labeled warning and precaution for approved oncology CAR T products.

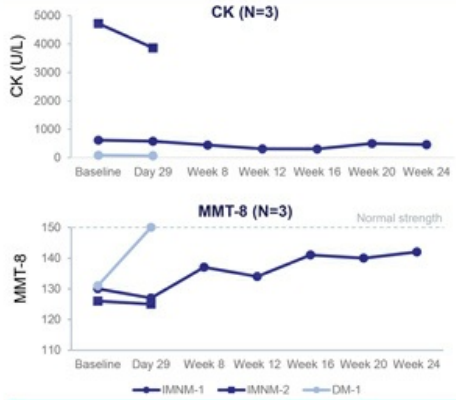
1. MIP-1β, IL-27
2. Nunez et al. Correlative Studies of CABA-201 from the RESET-Myositis™ and RESET-SLE™ Clinical Trials. Presented at ACR Convergence 2024. Abstract 0324

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; PE, pulmonary embolism; SAE, serious adverse event
Cabaletta Bio: Data on file.

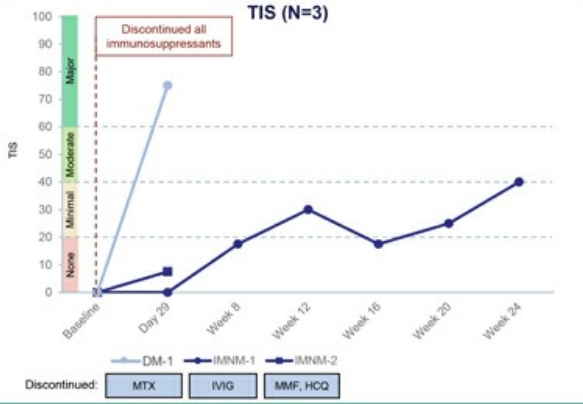
RESET-Myositis™: Efficacy data following rese-cel infusion

1st known adult DM patient dosed with CAR T demonstrated compelling early response off immunosuppressants‡

Disease activity & improvement measures



DM patient demonstrated a major TIS response at Day 29 & 1st IMNM patient showed a moderate TIS response at Week 24



Initial clinical responses in IMNM are consistent with published data[1]; response kinetics seem to differ among myositis subtypes

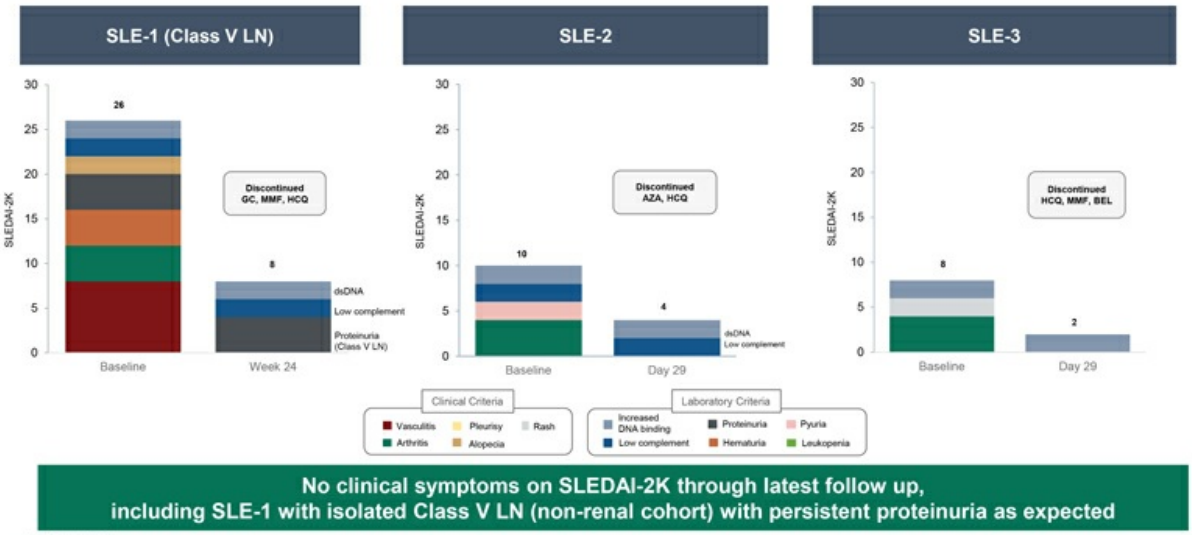
‡ As of Nov 1, 2024

Cabaletta Bio: Data on file. 1. Schett, G. 'CAR-T Cell Therapy: "The Future is Now."' 5th Global Conference on Myositis. iMyoS. Pittsburgh, PA.

Cabaletta Bio®

RESET-SLE™: Efficacy data in SLE following Rese-cel infusion

All 3 SLE patients demonstrated clinical responses off immunosuppressants; first patient completed steroid taper‡



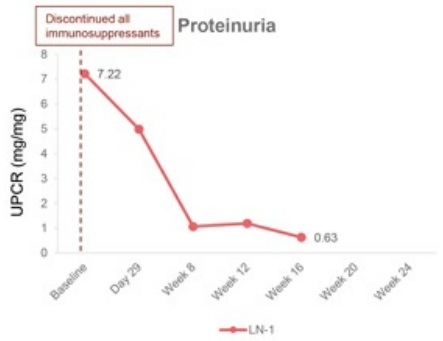
No clinical symptoms on SLEDAI-2K through latest follow up, including SLE-1 with isolated Class V LN (non-renal cohort) with persistent proteinuria as expected

‡ As of Nov 1, 2024
SLEDAI-2k, SLE disease activity index 2000.
Cabaletta Bio. Data on file.

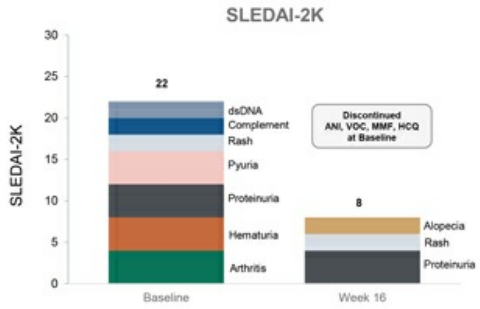
RESET-SLE™: Outcomes in first LN following rese-cel infusion

LN-1 demonstrated marked improvement of proteinuria off all immunosuppressants, continuing steroid taper‡

UPCR decreased from 7.22 to 0.63 mg/mg at Week 16



1st LN patient SLEDAI reduced by 14 points at Week 16



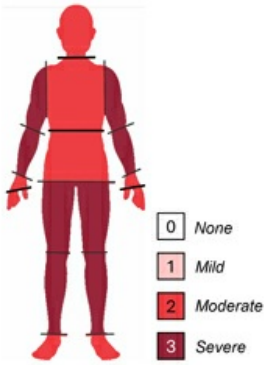
LN-1 proteinuria markedly improved by Week 8 with alopecia/rash as the remaining clinical manifestations at Week 16 after discontinuing all immunosuppressants & continuing prednisone taper

‡ As of Nov 1, 2024
SLEDAI-2k, SLE disease activity index 2000; UPCR, urinary protein-to-creatinine ratio.
Cabaletta Bio: Data on file.

Emerging efficacy data 42 days post infusion in first SSc patient

Early disease improvements in face and hands after discontinuation of disease-specific medication

Baseline mRSS score by body area[1]

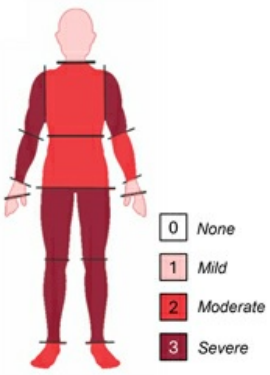


Overall mRSS score[1]

	Baseline	Day 22	Day 42
mRSS	42	38	36

- Modified Rodnan Skin Score (mRSS): a measure of skin thickness in SSc across 17 body areas, with a maximum score of 51[1]
- Used as an outcome measure in SSc clinical trials as a surrogate for disease activity, severity and mortality[1]

Day 42 mRSS score by body area[1]



Early clinical data in SSc-Skin-1 indicate potential emergence of a drug-free clinical response‡

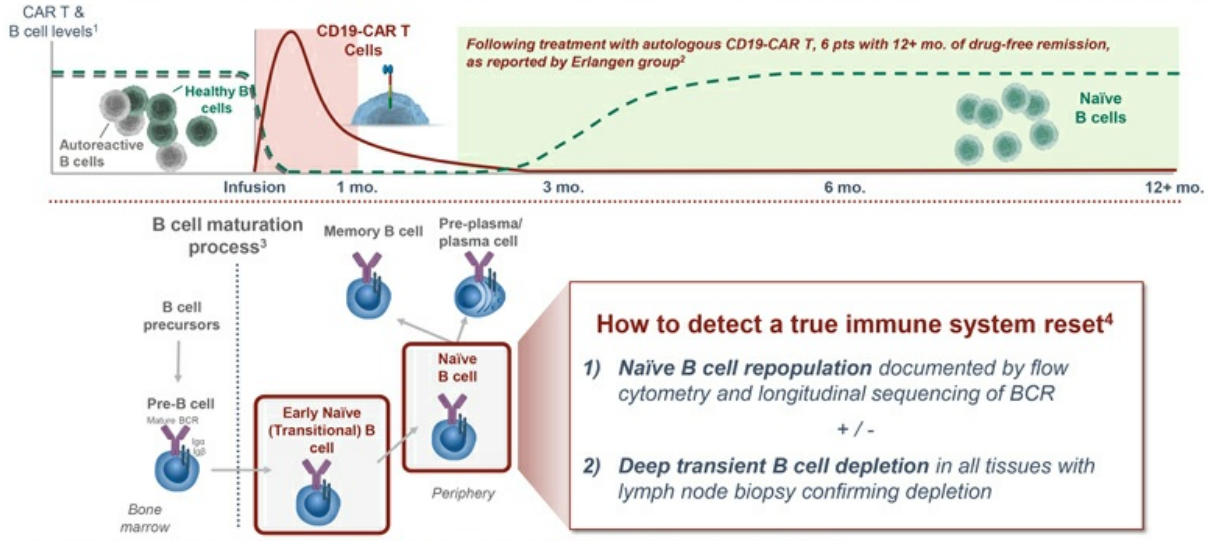
‡ As of Nov 1, 2024 patient is not taking immunosuppressants or steroids

Cabaletta Bio: Data on file. 1. Khanna D, et al. J Scleroderma Relat Disord. 2017;2(1):11–18.

Cabaletta Bio®

Achieving ‘immune system reset’ may predict long-term durability

Autologous CAR T is the only modality to date that has facilitated an immune system reset in autoimmune patients



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. Image adapted from Cambier JC, et al. *Nat Rev Immunol.* 2007;7(8):633-643.
4. Proposed mechanism for immune reset based on Cabaletta knowledge and assessment in the field

Cabaletta Bio®

Securing & expanding our leadership in autoimmune cell therapy

Several innovations to prioritize patient experience, expand access and address scale in autoimmune disease

Product/Process Innovations in development

- **Evaluating rese-cel in PV without preconditioning**
  - Both published data and experience with legacy CAART platform suggest that preconditioning may not be necessary in autoimmune patients[1,2]
  - As a well-defined autoantibody-mediated disease, PV is a potentially ideal evaluation setting
  - Expected to present clinical data from the RESET-PV trial in 2025
- **Advancing whole blood program to remove the burden of apheresis[3]**
- **Minimizing the requirement for inpatient stay**
- **IND application cleared for RESET-MS trial in patients with multiple sclerosis (MS)**
  - RESET-MS is a Phase 1/2 dose-escalation study in relapsing MS and progressive MS
  - FDA has granted Fast Track Designation to rese-cel for the treatment of relapsing MS and progressive MS

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. Poster P0744: Clinical and translational findings following MuSK-CAART infusion without preconditioning in patients with Myasthenia Gravis (MuSCAARTes™ trial). ESGCT 2024.
3. Abstract 1372: Autologous CD19 CART Manufacturing from Whole Blood Collection for the Treatment of Autoimmune Disease. ASGCT 2024.

Manufacturing strategy – securing reliable supply then innovating

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

Clinical & Commercial Supply:
Penn, CDMOs & CABA Process

- Penn has reliably provided timely product for years
- WuXi partnership provides additional rese-cel supply
- Advancing paths to commercial-ready manufacturing:
  - ✓ Expansion of CDMO partnerships for pivotal supply

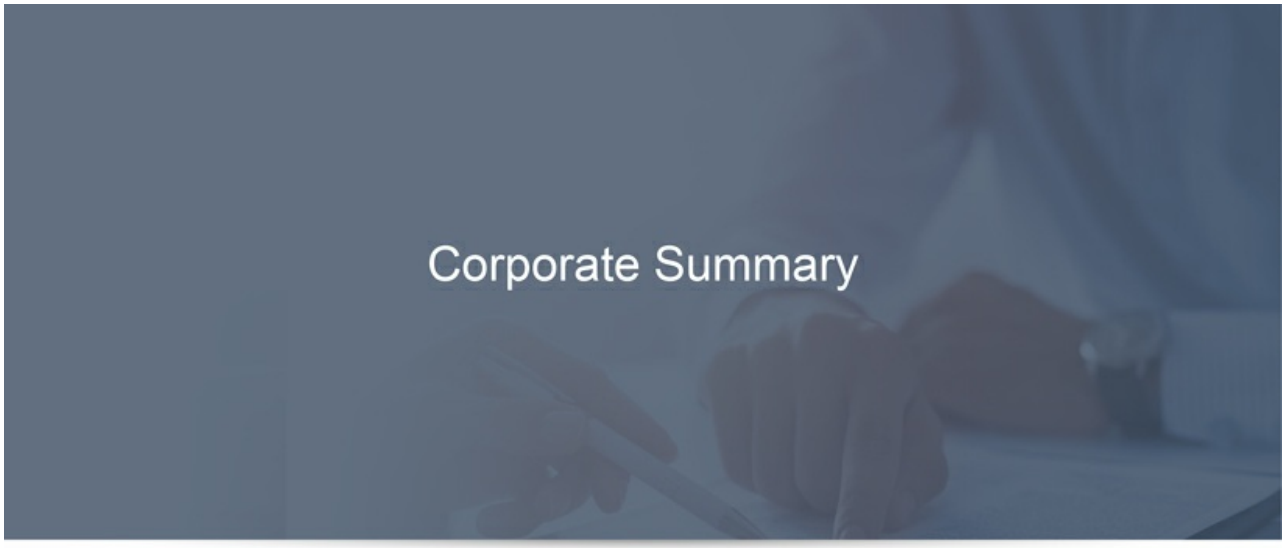
    Lonza
  - ✓ Partnered with commercial supplier for vector

    Oxford Biomedica
  - Future consideration – Cabaletta-operated facility
  - Opportunity for strategic partnership(s)

Innovative Manufacturing:
Scale-Up & Reduced COGs

- Expanded partnerships for automated manufacturing

  CELLARES
- Continuous focus on innovations to address scale:
  - Further closing and automating our commercial process
  - Advancing Cellares technology assessment program
  - Evaluating whole blood process to eliminate apheresis



Cabaletta Bio®

Cabaletta Bio leadership

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

LEADERSHIP TEAM

Steven Nichtberger, M.D.
President, CEO & Chairman

Samik Basu, M.D.
Chief Scientific Officer

Gwendolyn Binder, Ph.D.
President, Science & Technology

David J. Chang, M.D., M.P.H., FACR
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Chief Business Officer

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Heather Harte-Hall
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Anup Marda
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Nicolette Sherman
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Gerwin Winter
Head of International

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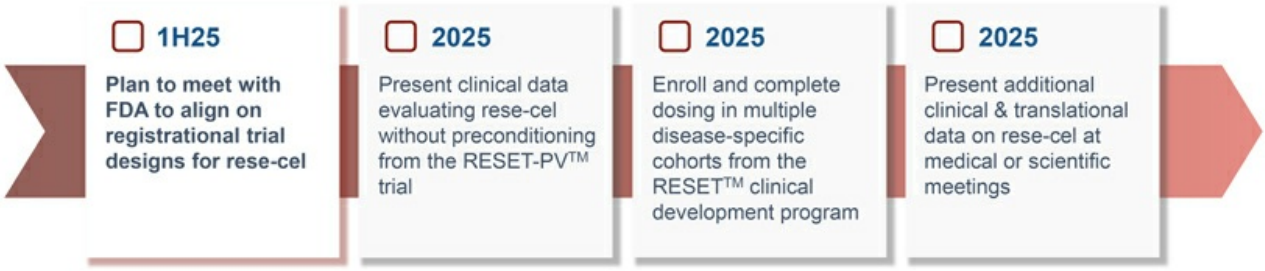
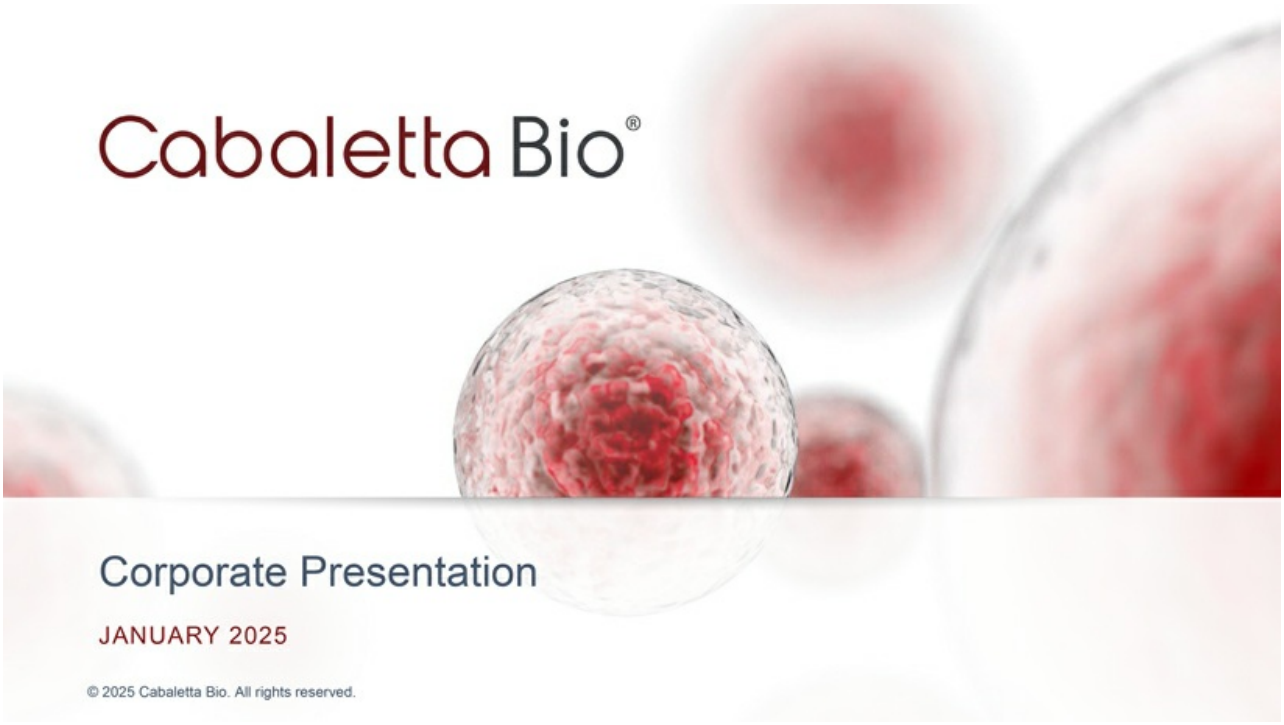
Jay Siegel, M.D.

Drew Weissman, M.D., Ph.D.

Cabaletta's Anticipated Key Milestones for 2025





Cabaletta Bio®

Corporate Presentation

JANUARY 2025

Cabaletta Bio®

Cabaletta Bio Outlines Strategic Priorities and Anticipated Key Milestones for 2025

– Company plans to meet with the FDA to align on registrational trial designs in 1H25 based on emerging clinical profile of resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) and increased pace of enrollment with 44 active clinical trial sites –

– Favorable safety profile observed across the first 10 patients dosed with rese-cel: 90% experienced either no CRS or grade 1 (fever) CRS and 90% experienced no ICANS; latest clinical and translational data to be presented at a scientific meeting in February 2025 –

– First patient enrolled in the RESET-PV™ trial evaluating rese-cel without preconditioning –

– First site opened in the juvenile myositis cohort of RESET-Myositis™ trial –

– IND application for rese-cel cleared for the RESET-MS™ trial in multiple sclerosis with Fast Track Designation –

PHILADELPHIA, Jan. 13, 2025 — 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 announced recent pipeline and operational progress and outlined its strategic priorities and anticipated key milestones for 2025.

"Our clinical execution in 2024 allowed us to accelerate timelines for registrational discussions and demonstrate the potential of rese-cel to deliver immunosuppressant-free, compelling clinical responses in patients with active, refractory autoimmune disease. During the first half of 2025, our top priorities are clinical execution and achieving alignment with the FDA on the registrational pathway for rese-cel based on rapidly emerging clinical and translational data," said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. "Leveraging a large and growing clinical site footprint in the U.S., recent expansion into Europe and an increased pace of patient enrollment observed across the RESET™ clinical development program since our presentations at ACR Convergence in November 2024, we look forward to building on our momentum as we move closer to realizing our vision of launching the first targeted curative cell therapy designed specifically for patients with autoimmune disease."

Recent Pipeline and Operational Progress

- As of December 31, 2024, 21 patients have been enrolled across 44 actively recruiting clinical sites in the U.S. and Europe across the RESET clinical development program.
- In the first 10 patients dosed with rese-cel with at least one month offollow-up, 90% have experienced either no cytokine release syndrome (CRS) or grade 1 (fever) CRS and 90% have experienced no immune effector cell-associated neurotoxicity syndrome (ICANS). Data from these patients will be presented at an upcoming scientific meeting in February 2025.

- Today, Cabaletta announced the following progress in support of its commitment to advance innovations that improve the patient and physician experience, in addition to broadening the potential of rese-cel for patients:
    - The first patient has been enrolled in the RESET-PV trial, evaluating rese-cel without preconditioning in patients with pemphigus vulgaris.
    - The first juvenile myositis clinical site in the RESET-Myositis trial is now open and actively recruiting. The U.S. Food and Drug Administration (FDA) previously granted Rare Pediatric Disease designation for rese-cel in juvenile dermatomyositis.
    - The first patient has been enrolled in the RESET-MG™ trial, evaluating rese-cel in patients with myasthenia gravis.
    - The Investigational New Drug (IND) application for rese-cel has been allowed to proceed within the routine30-day window by the FDA for the RESET-MS trial, a Phase 1/2 study evaluating rese-cel in patients with multiple sclerosis (MS). In addition, the FDA has granted Fast Track Designation to rese-cel for the treatment of relapsing and progressive forms of MS.
- In order to expand our clinical supply to address the increasing pace of enrollment in our clinical trials as well as to prepare for registrational trial(s) across the RESET clinical development program while expanding our manufacturing options for rese-cel, Cabaletta has expanded its CDMO agreement with Lonza, a leading Contract Development and Manufacturing Organization (CDMO), to supply rese-cel clinical product under current Good Manufacturing Practices as soon as the second half of 2025.
- In November 2024, Cabaletta presented new and updated clinical data on rese-cel supporting its potential to achieve drug-free, compelling clinical responses based on eight patients dosed across the ongoing Phase 1/2 RESET-Myositis, RESET-SLE™ and RESET-SSc™ clinical trials at the American College of Rheumatology (ACR) Convergence 2024 conference.

Strategic Priorities and Anticipated Key Milestones for 2025

Gain alignment with the FDA on a path to registration for rese-cel that leverages our indication-specific trials to rapidly advance registrational programs

- The Company now plans to meet with the FDA regarding registrational trial designs for rese-cel in the first half of 2025 based on the emerging clinical and translational data and increased pace of enrollment.

Enroll patients and complete dosing in multiple disease-specific cohorts across the RESET clinical development program

- Present new and updated clinical and translational data on rese-cel throughout 2025.

Continue advancing innovations designed to expand patient access and provide streamlined and positive experiences with rese-cel for patients and providers

- **Evaluate rese-cel with no preconditioning:** Generate clinical and translational data evaluating rese-cel without preconditioning from the RESET-PV trial in 2025.
- **Align with FDA on whole blood replacement for apheresis:** Continue to advance the whole blood manufacturing program as a potential replacement for apheresis and seek to align with FDA on a strategy to incorporate it into the RESET clinical development program.

Financial Guidance

Cabaletta ended the fourth quarter of 2024 with unaudited cash and cash equivalents of $164 million. The Company expects that this cash position as of December 31, 2024 will enable it to fund its updated operating plan, including recently accelerated clinical assumptions, into the first half of 2026.

About the RESET-MS™ Trial

The RESET-MS™ trial is a Phase 1/2 open-label, dose escalation study of rese-cel in subjects with relapsing and progressive forms of multiple sclerosis (MS), evaluated in separate cohorts. Subjects will receive a one-time infusion of rese-cel following a preconditioning regimen of fludarabine and cyclophosphamide. Key inclusion criteria for the relapsing MS cohort include patients between ages 18 to 60 (inclusive), evidence of clinical relapse during the previous 2 years, and prior treatment with a high efficacy therapy for at least 6 months. Key progressive MS inclusion criteria include patients between ages 18 to 60 (inclusive) and evidence of objective disease worsening during the prior year while on standard of care therapy for at least 6 months. Key exclusion criteria for both cohorts include history of fulminant MS within 5 years, a prior history of seizures or other clinically significant concomitant CNS pathology, history of progressive multifocal leukoencephalopathy, as well as treatment with a B cell depleting agent within the prior approximately 20 weeks.

About rese-cel (formerly referred to as CABA-201)

Rese-cel is a 4-1BB-containing fully human CD19-CAR T cell investigational therapy for patients with autoimmune diseases where B cells contribute to the initiation and/or maintenance of disease. Following a one-time infusion of a weight-based dose, rese-cel is designed to transiently and completely deplete all CD19-positive cells. This approach has the potential to reset the immune system and result in compelling clinical responses without chronic therapy requirements in patients. Cabaletta is currently evaluating rese-cel in the RESET™ (REstoring SElf-Tolerance) clinical development program which includes multiple disease-specific, company-sponsored clinical trials across growing portfolios of autoimmune diseases in a broad range of therapeutic areas, including rheumatology, neurology and dermatology.

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases. The CABA™ platform encompasses two complementary strategies which aim to advance the discovery and development of engineered T cell therapies with the potential to become deep and durable, perhaps curative, treatments for a broad range of autoimmune diseases. The lead CARTA (Chimeric Antigen Receptor T cells for Autoimmunity) strategy is prioritizing the development of rese-cel, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy. Rese-cel is currently being evaluated in the RESET™ (REstoring SElf-Tolerance) clinical development program spanning multiple therapeutic areas, including rheumatology, neurology and dermatology. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA. For more information, please visit www.cabalettabio.com and connect with us on LinkedIn.

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 business plans and objectives as a whole; Cabaletta's ability to realize its vision of launching the first curative targeted cell therapy designed specifically 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, including the timing and results of Cabaletta's clinical trials and its ability to conduct and complete clinical trials; expectation that clinical results will support rese-cel's safety and activity profile; statements regarding the timing of interactions with regulatory authorities, including such authorities' review of safety information from Cabaletta's ongoing clinical trials and potential registrational pathway for rese-cel; Cabaletta's expectations around the potential success and therapeutic benefits of rese-cel, including its belief that rese-cel has the potential to reset the immune system and result in compelling clinical responses without chronic therapy requirements in patients; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel in patients with SLE, myositis, SSc and gMG and advancement of the RESET-PV and RESET-MS trials, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; the clinical significance of the clinical data read-out at upcoming scientific meetings; Cabaletta's ability to expand its clinical supply for registrational trial(s) across the RESET clinical development program as well as to expand its manufacturing options for rese-cel; Cabaletta's ability to increase enrollment in its US and Europe clinical networks; Cabaletta's ability to leverage its growing clinical trial network to accelerate development of its therapy for patients and to generate clinical and translational data; Cabaletta's advancement of the whole blood manufacturing program as a potential replacement for apheresis as well as its potential alignment with FDA in connection thereto; and Cabaletta's use of capital, expense and other financial results in the future and its ability to fund operations into the first half of 2026.

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 rese-cel; 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 rese-cel; 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; 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 subsequent 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.

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