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

February 18, 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 7.01 Regulation FD Disclosure

On February 18, 2025, Cabaletta Bio, Inc. (the "Company" or "Cabaletta") posted to the "Investors & Media" section of the Company's website at *www.cabalettabio.com* an updated corporate presentation providing a corporate overview and updated development plan (the "Corporate Presentation"). A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

On February 18, 2025, the Company also issued a Press Release announcing new and updated clinical data from the first 10 patients dosed with resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) across the RESET clinical development program (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 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On February 18, 2025, the Company issued the Press Release announcing new and updated clinical data from the first 10 patients dosed with resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) across the RESET clinical development program.

Cabaletta is currently evaluating rese-cel in the RESET (REstoring SElf-Tolerance) clinical development program, which includes six company-sponsored Phase 1/2 clinical trials with disease-specific cohorts, spanning the therapeutic areas of rheumatology, neurology and dermatology. All cohorts are evaluating a weight-based single infusion of rese-cel following a preconditioning regimen of fludarabine and cyclophosphamide, except for the RESET-PV™ trial, which is evaluating weight-based dosing of rese-cel without preconditioning.

New and Updated Clinical Data Summary

As of the data cut-off date of January 8, 2025, 10 patients had been dosed with rese-cel across the RESET-Myositis™, RESET-SLE™ and RESET-SSc™ trials with sufficient follow-up to be evaluable, providing the following key insights:

- In the RESET-Myositis trial, the first adult dermatomyositis patient maintained a major total improvement score (TIS) improvement at 3 months post-infusion, off all immunosuppressants and steroids, showing potential for achieving drug-free remission in patients with refractory myositis. In addition, initial clinical responses in the first 2 immune-mediated necrotizing myopathy (IMNM) patients continued to show more gradual improvement, consistent with published academic data, suggesting response kinetics may differ among myositis subtypes.
- In the RESET-SLE trial, 3 out of 4 patients in the non-renal systemic lupus erythematosus (SLE) cohort achieved DORIS (definition of remission in SLE) remission as of the most recent follow-up visit. The first patient dosed with rese-cel in the lupus nephritis (LN) cohort achieved a complete renal response (CRR). All 6 SLE and LN patients dosed, including these patients, demonstrated clinical responses off all immunosuppressants and steroids as of the data cut-off date.
- In the RESET-SSc trial, the first patient dosed with rese-cel in the severe skin cohort continued to demonstrate clinically meaningful skin improvements across an increasing number of body areas at 3 months post-infusion, in addition to improvement in lung function, after discontinuing all disease-specific therapies.

- Rese-cel consistently demonstrated deep depletion of B cells in the periphery within the first month of infusion. Tissue resident depletion consistent with the deep B cell depletion in circulation was confirmed by a lymph node biopsy in a systemic sclerosis patient. B cell repopulation has typically started around 2 months post-infusion and exhibited a transitional naïve phenotype, reflecting the production of new B cells after deep systemic depletion.
- Across the first 10 patients dosed withrese-cel with at least one month offollow-up, 90% experienced either no cytokine release syndrome (CRS) or grade 1 CRS (fever) and 90% experienced no immune effector cell-associated neurotoxicity syndrome.

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 profound 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 belief that its expanding clinical experience with rese-cel underscores its potential to provide compelling clinical responses without the need for immunosuppressants or steroids in patients with active, refractory autoimmune disease, as well as its belief that rese-cel has the potential to transform the disease outcome and the lives of patients with autoimmune disease; and Cabaletta's belief that its growing number of sites will allow it to continue accelerating the pace of enrollment and dosing across the RESET program, further enabling it to evaluate the emerging clinical profile of rese-cel and its therapeutic potential for autoimmune patients.

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 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	Investor Presentation, dated February 18, 2025, furnished herewith.
99.2	Press Release issued by the registrant on February 18, 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: February 18, 2025

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

Exhibit 99.1

Cabaletta Bio®

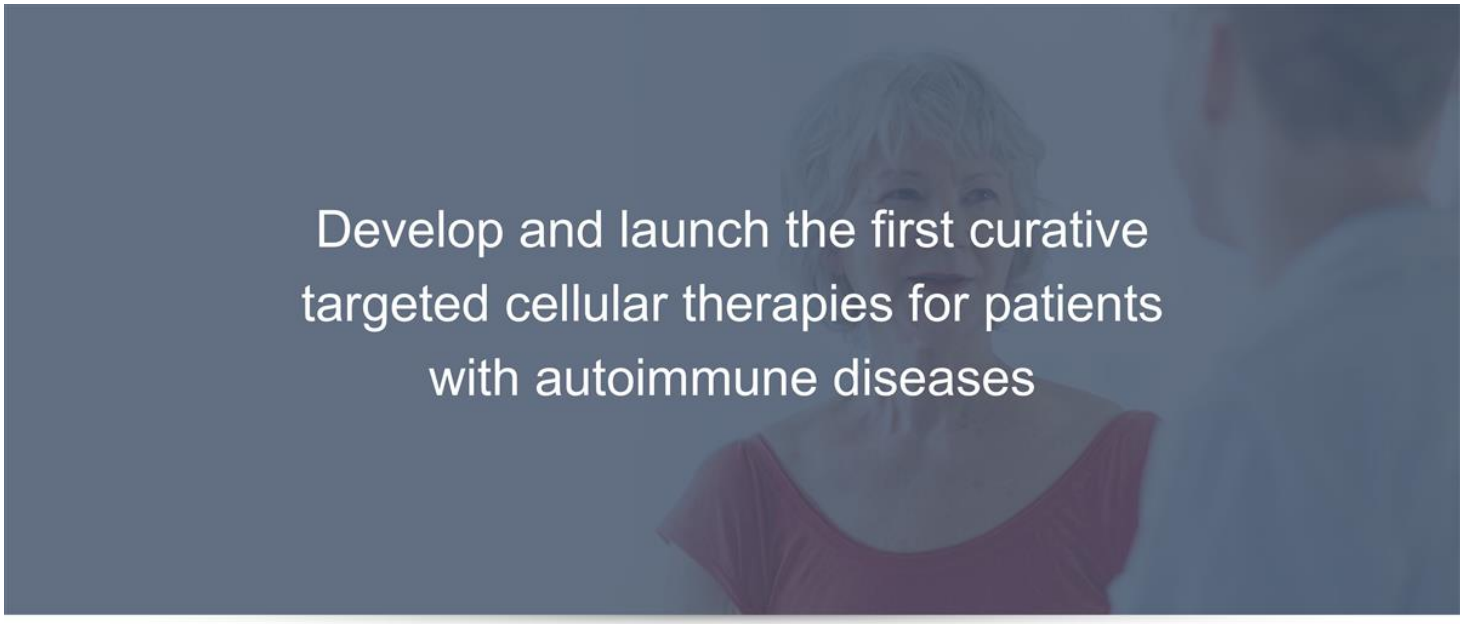
Corporate Presentation

FEBRUARY 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 has the potential to provide drug-free, durable meaningful clinical responses, through an immune reset, including the potential for achieving drug-free remission in patients with refractory myositis; 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 timing thereof, 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 to remove the burden of apheresis; 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 to approval and launch 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: Pursuing an efficient path to approval

Planning to leverage increasing clinical data and unique development program for rese-cel[1]

Compelling clinical efficacy with favorable safety profile & deep B cell depletion

- **Deepening clinical efficacy** data over-time with **immunosuppressant and steroid-free outcomes[2]:**
  - DORIS remission in 3 SLE patients
  - Complete renal response in 1st LN pt
  - Major TIS response in 1st DM patient
- **Favorable safety profile** in 1st 10 patients
  - 90% either no CRS or Grade 1 CRS
  - 90% no ICANS
- **Deep systemic B cell depletion** observed in the periphery and confirmed in the tissue in scleroderma patient by lymph node biopsy

Unique development strategy designed to accelerate time to approval and launch

- **Multiple disease-specific trials** with a common design allow for generation of disease-specific efficacy data with shared safety database
- **Weight-based dose, single infusion**; supported by clinical & translational data[2]
- **Industry-leading clinical network:**
  - 50 active US and European sites
  - 26 patients enrolled
  - Enrolling ~1 pt/week since Nov. 2024[3]

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

- **Meeting scheduled with FDA to align on registrational trial designs in 1H25 for rese-cel**
- **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

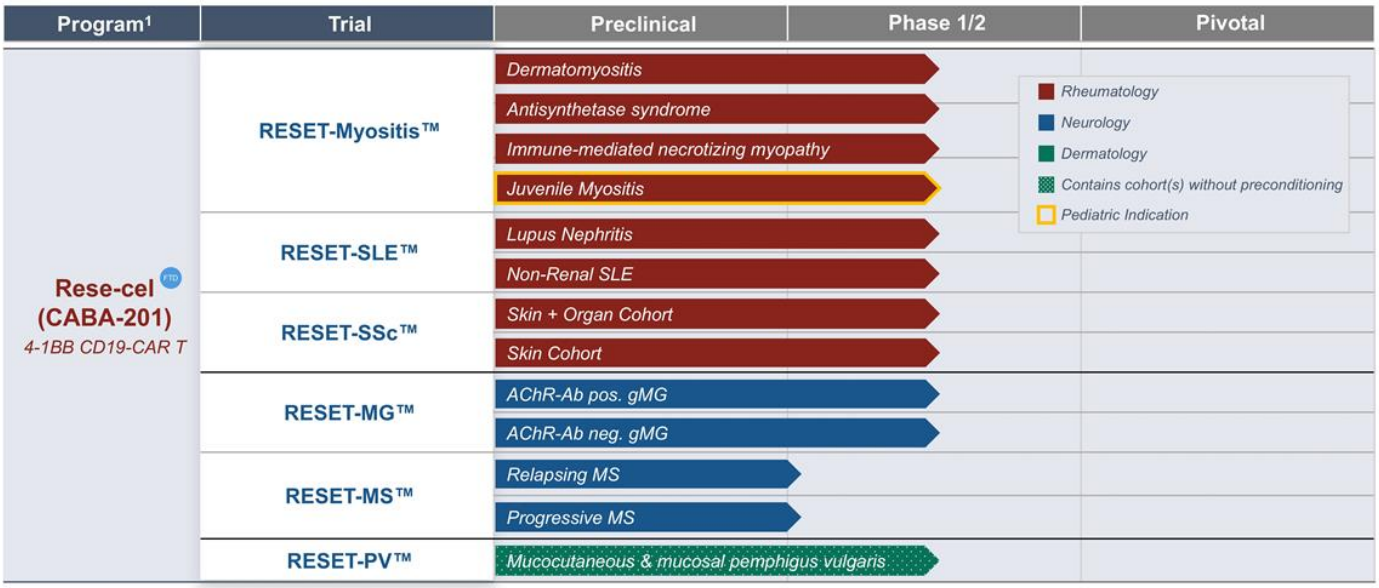
Patients are seeking a drug-free, symptom-free life which is rarely achieved despite current therapies; physicians also prioritize prevention of end-organ damage[4]

CRS, cytokine release syndrome; DM – dermatomyositis; DORIS – definition of remission in SLE; ICANS, immune effector cell-associated neurotoxicity syndrome; LN – lupus nephritis; PK – pharmacokinetic; PD – pharmacodynamic; SLE – systemic lupus erythematosus; TIS – total improvement score.

1. resecabtagene autoleucel; CABA-201
2. As of Jan 8, 2025.
3. As of Feb 13, 2025.
4. Golder, et al. Lupus. 2018;27(3): 501-506

Innovative clinical strategy with potential for accelerated regulatory path

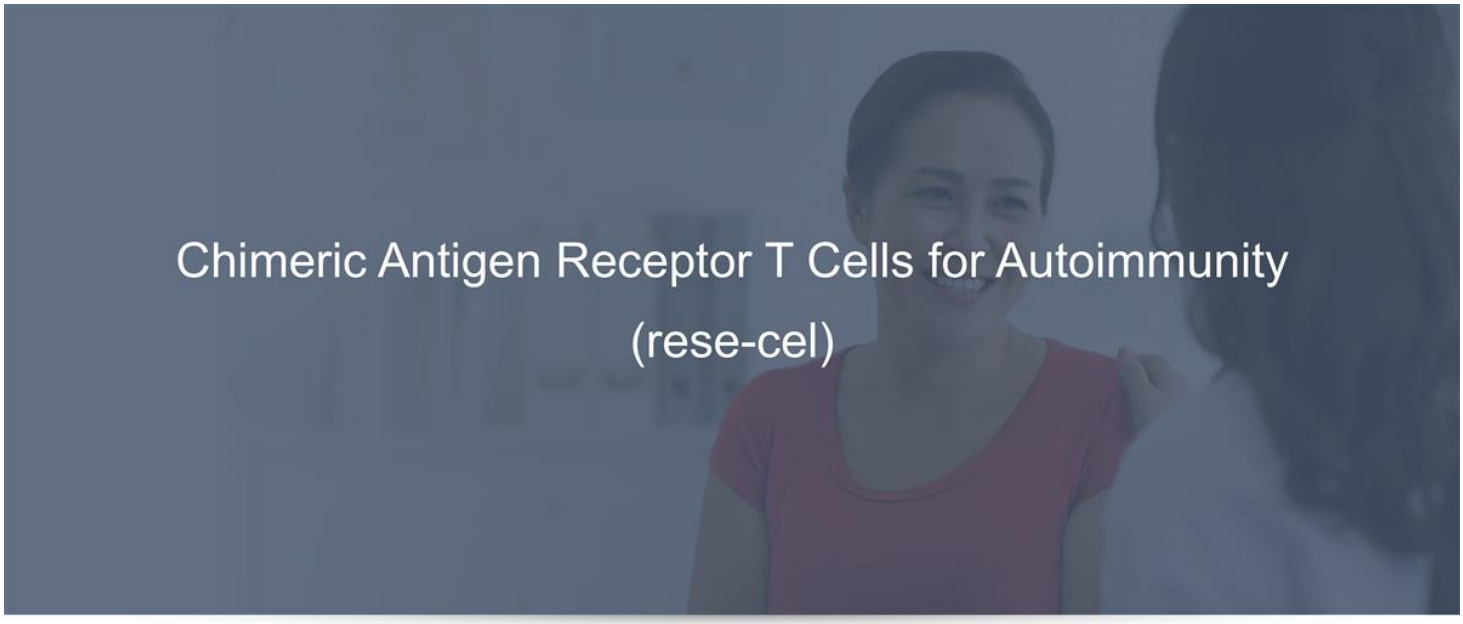
RESET clinical program has disease-specific cohorts designed to evolve directly into registrational studies



RESET™ – **RE**storing **SE**lf-**T**olerance; 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.

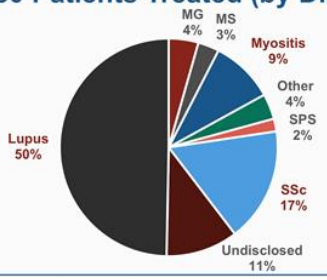


Cabaletta Bio®

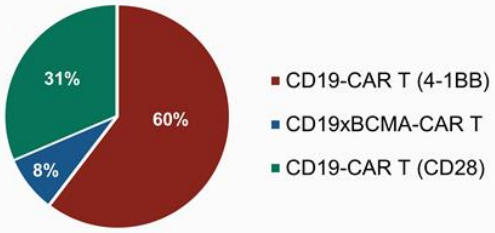
Autologous CAR T is potentially transformational for autoimmunity

~150 autoimmune patients have been dosed with a range of autologous CAR T constructs (industry & academia)[1]

~150 Patients Treated (by Disease)



Type of CAR T Construct



Safety Observations[1]

- Among ~150 autoimmune patients dosed with cell therapy, frequency and severity of CRS/ICANS events were considerably lower than those observed in cancer patients
  - <2% Gr 3+ CRS & Gr 3+ ICANS events observed
- Vaccine titers stable with CD19-CAR T mono-targeting therapy
  - insufficient data with CD19xBCMA-CAR T

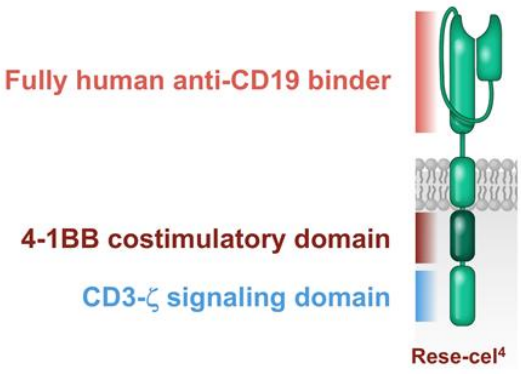
Efficacy Observations[1]

- Compelling immunosuppressant-free clinical responses observed across many autoimmune diseases, durable for up to 4 years
- Clinical recurrences observed in <5% of ~150 treated patients
  - IIM patient relapsed after 12+ months of drug-free remission
    - No evidence of CD19 escape or failure
    - Patient treated with BCMA-CAR T & now in remission[2]

IIM – idiopathic inflammatory myopathy; MG – Myasthenia gravis; MS – Multiple sclerosis; SPS – Stiff person syndrome; SSc – Systemic sclerosis.
Note: 'Other' indications includes CIDP, IgG4-related disease, ANCA-associated vasculitis, NMOSD, Lambert Eaton myasthenic syndrome, autoimmune encephalitis.
1. Data as of November 2024 (ACR Convergence 2024) based on Cabaletta Bio literature review across industry and academia.
2. Abstract 1749: Safety and Long-term Efficacy of CD19-CAR T-cell Therapy in 30 Patients with Autoimmune Disease. ACR Convergence 2024.

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. Maschan, Michael, et al. "Multiple site place-of-care manufactured anti-CD19 CAR-T cells induce high remission rates in B-cell malignancy patients." Nature Communications 12, 7200 (2021) 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

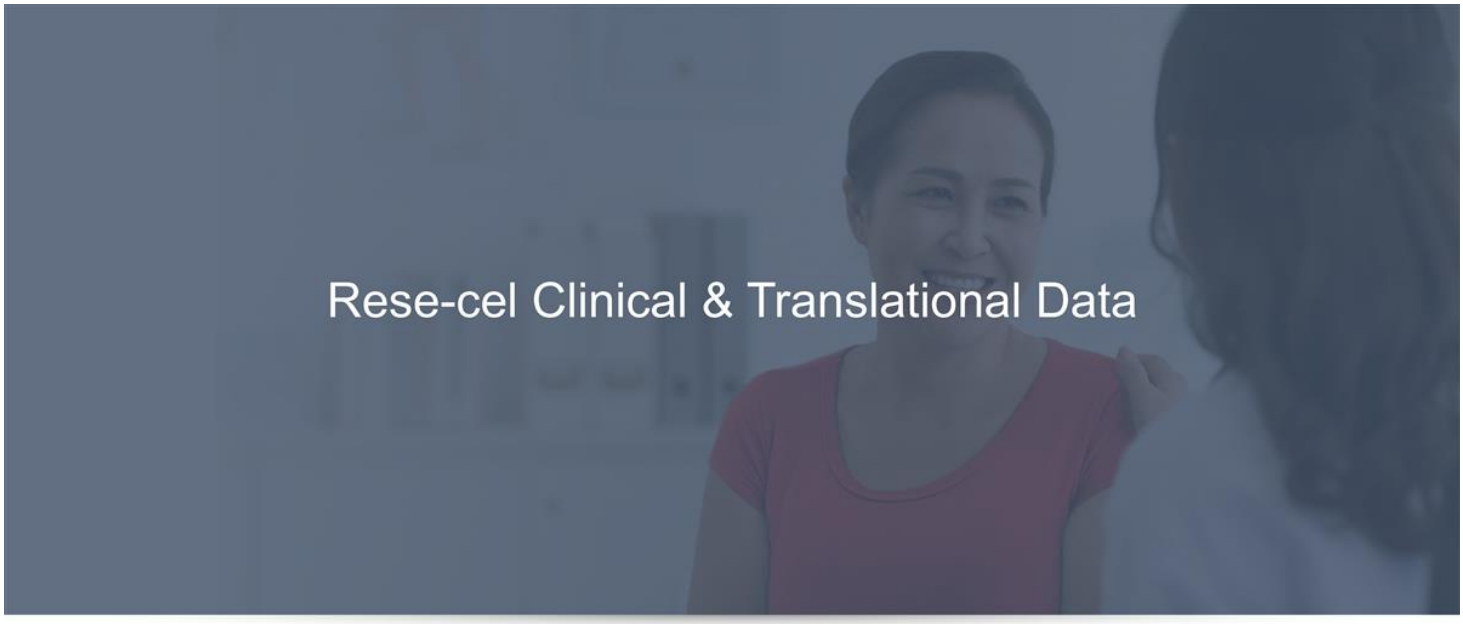
Broad portfolio with six RESET trials designed to address high unmet need and realize the potential of rese-cel

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					
~70k	**~160-320k**	**~90k**	**~55k**	**~750k**	**~15k**
EU Prevalence					
~85k	**~150k**	**~60k**	**~100k**	**~550k**	**~20k**

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



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™

- Diagnosis of IIM (**ASyS, DM, or IMNM**)
- Age ≥18 and ≤75
- Presence of at least one myositis antibody
- **JIIM**: Age ≥6 and ≤17 with presence of at least one MSA or MAA

RESET-SLE™

- Diagnosis of SLE (**SLE or LN**)
- Age ≥18 and ≤65
- Positive ANA or anti-dsDNA at screening
- **SLE (non-renal)**: active, moderate to severe SLE, SLEDAI-2K ≥8; pure class V LN eligible
- **LN**: active, biopsy-proven LN class III or IV (± class V)

RESET-SSc™

- Diagnosis of **SSc limited or diffuse**
- Age ≥18 and ≤70
- 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

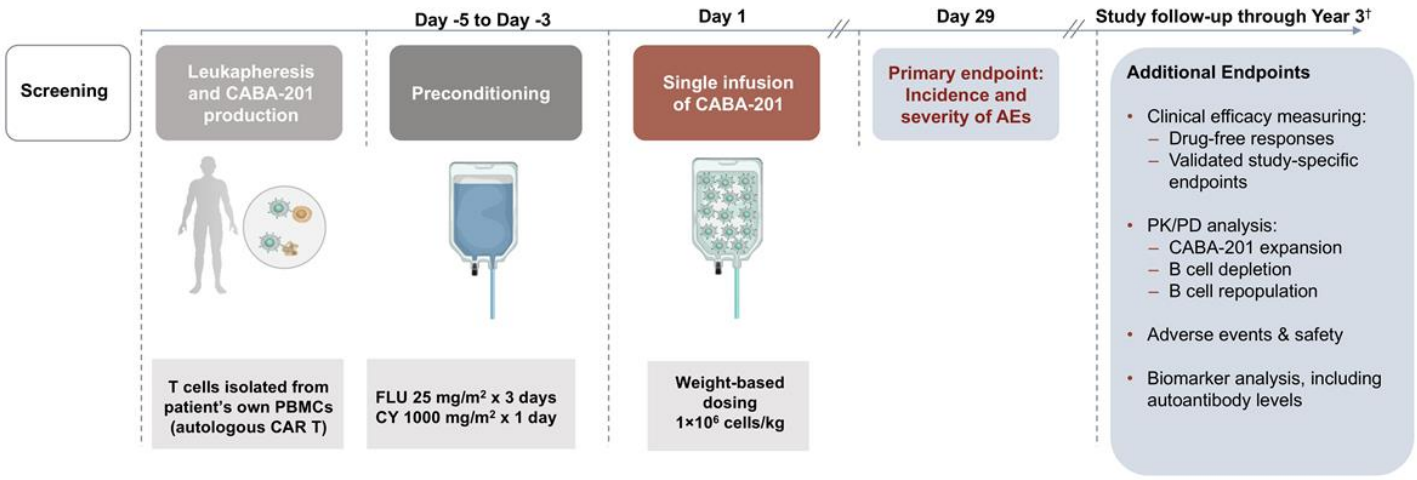
Anticipate enrolling and completing dosing in multiple disease-specific cohorts in 2025; similarly designed RESET-MG™ Phase 1/2 trial enrolling

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).

RESET™ clinical trials have consistent design principles[1]

Individual trials in myositis, SLE, and SSc share common elements of preconditioning, dose, and study design



†Follow up period encompasses 15 years in total, aligned to regulatory guidance for CAR T cell therapies.
AE, adverse event; CABA, Cabaletta Approach to B cell Ablation; FLU, fludarabine; CY, cyclophosphamide; PBMC, peripheral blood mononuclear cell; PD, pharmacodynamics; PK, pharmacokinetics; RESET, REstoring SElf-Tolerance; SLE, systemic lupus erythematosus; SSc, systemic sclerosis.
Cabaletta Bio: Data on file; 1. Peng BJ, et al. Mol Ther Methods Clin Dev. 2024;32(2):101267.

Baseline characteristics of first 10 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**	**SLE-4**	**LN-1**	**LN-2**	**SSc-Skin-1** Severe skin cohort
Age, sex	33 M	60 M	57 M	26 M	36 F	44 F	37 F	24 F	35 F	66 F
Disease duration (y)	~2	~4	~4	~6	~17	~9	~10	~2	~8	~2
Autoantibodies	SRP	HMGCR	SAE	dsDNA	dsDNA	dsDNA	dsDNA	dsDNA	dsDNA	RNA P III
Baseline Disease activity*	**MMT-8**			**SLEDAI-2K**						**mRSS**
	130	126	131	26	10	8	8	22	14	42
	CK (U/L)			**UPCR (mg/mg)**						
	617	4725	94	1.08†	n/a	n/a	n/a	7.22	4.85	
Therapies at Screening	GC, MTX	GC, IVIG	GC, MMF, HCQ	HCQ, GC, MMF	GC, AZA	HCQ, MMF, BEL	HCQ‡	HCQ, GC, MMF, ANI, VOC	MMF	MMF, BRX
Other prior therapies	RTX, IVIG	RTX, MMF, MTX	IVIG	CYC, BEL, VOC, TAC	HCQ, MTX, ANI, BEL, MSC, RTX, ADA	GC, MTX	MTX, BEL	BEL, LEF	HCQ, GC, AZA, RTX	HCQ
GC dose at Screening (mg/day)#	5	5	20	10	7	n/a	n/a‡	20	N/A	N/A

*Baseline disease activity = activity before preconditioning. #Prednisone/prednisone equivalent dose

†SLE-1 had class V LN; inclusion criteria for LN cohort requires class III/IV LN. ‡SLE-4 initiated 20 mg/day of prednisone after screening and before leukapheresis, tapered to 2.5mg by latest follow-up of week 8 and discontinued as of data cut.

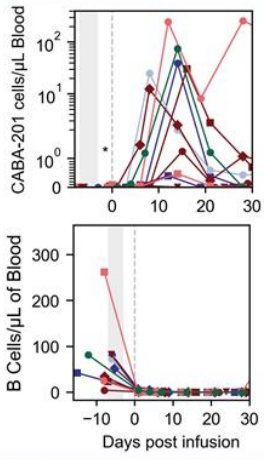
ADA, adalimumab; ANI, anifrolumab; AZA, azathioprine; BEL, belimumab; BRX, brentuximab vedotin; CK, creatinine kinase; CYC, cyclophosphamide; dsDNA, double-stranded DNA; GC, glucocorticoid; HCQ, hydroxychloroquine; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IVIG, intravenous immunoglobulin; LEF, leflunomide; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; mRSS, modified Rodnan skin score; MSC, mesenchymal stem cell; MTX, methotrexate; RESET, REstoring SElf-Tolerance; RNA P III, RNA polymerase III; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SLEDAI-2K, SLE disease activity index 2000; SRP, signal recognition particle; TAC, tacrolimus; U/L, units per liter; UPCR, urinary protein-to-creatinine ratio; VOC, voclosporin, y, years.

Cabaletta Bio: Data on file.

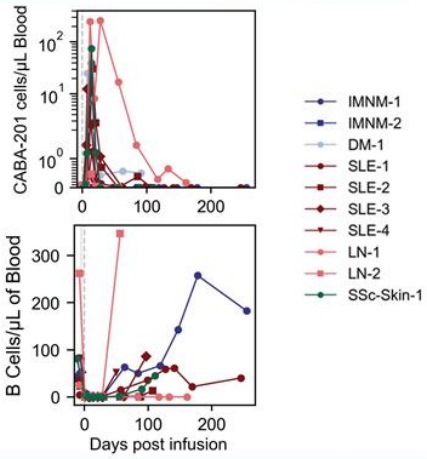
Consistent and deep B cell depletion by Day 22[1]

B cell repopulation with transitional naïve cells started as early as 2 months post-infusion

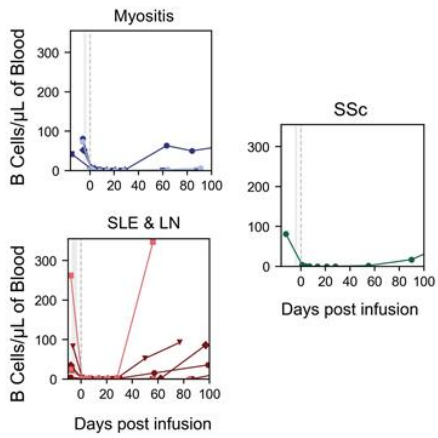
Peak expansion typically day 8 to 15; B cell depletion by day 22



B cell repopulation as early as 8 weeks post-infusion



B cell repopulation across all indications to date

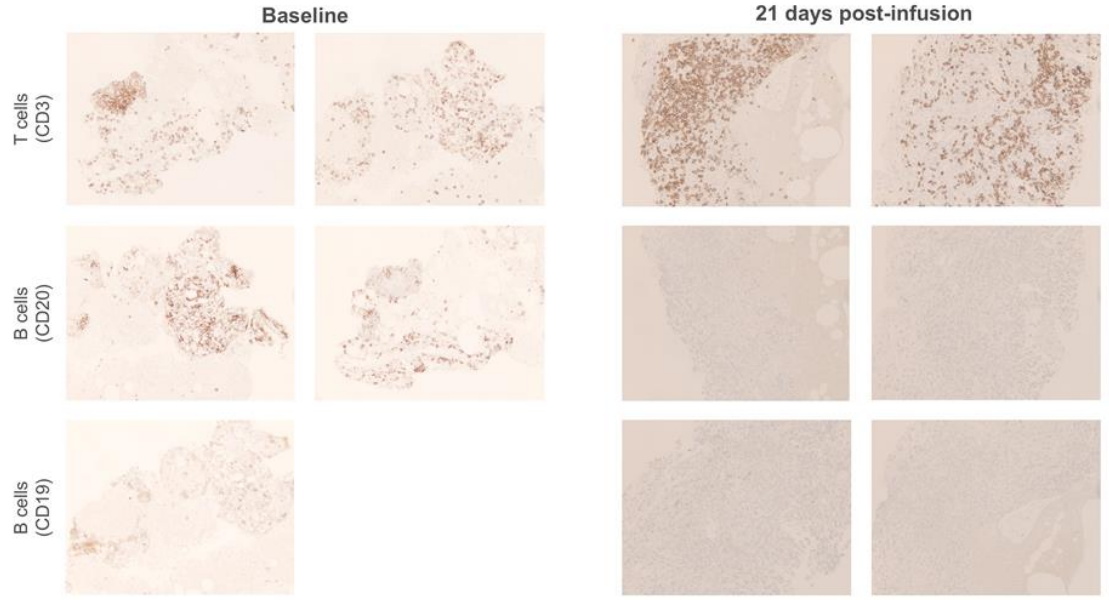


Rese-cel exhibited a PK/PD profile with peak expansion between Day 8 and 15 as expected, with a later 2nd peak for the first LN patient, suggestive of a possible occult infection[1]

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

Lymph node B cell depletion 21 days post infusion in first SSc patient

Tissue resident depletion, consistent with the deep B cell depletion in circulation, observed via lymph node biopsy



1. LN biopsies were from the left inguinal area using USG at U. Michigan by Dr. Khanna
2. All Images are 20X magnification

Incidence and severity of adverse events in the first 10 patients*

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

***Prior to infusion, LN-1 patient experienced acute, febrile inflammatory events & highly elevated pro-inflammatory cytokines[1] 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 Jan 8, 2025; Primary endpoint is incidence and severity of adverse events through Day 29. †Graded per ASTCT Consensus Grading Criteria. Of these patients, DM-1, SLE-2, SLE-3, SLE-4, LN-2, 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.

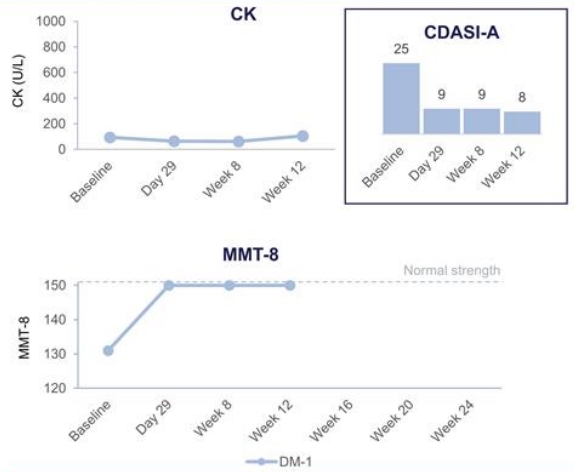
1. MIP-1β, IL-27
2. Nunez et al. Correlative Studies of CABA-201 from the RESET-Myositis™ and RESET-SLE™ Clinical Trials. Presented at ACR Convergence 2024. Abstract 0324

CRS, cytokine release syndrome; CY, cyclophosphamide; FLU, fludarabine; ICANS, immune effector cell-associated neurotoxicity syndrome; 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 maintained a major TIS response at Week 12

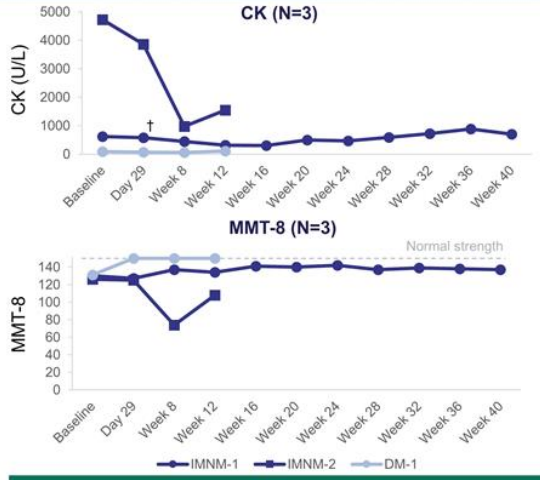
Maintenance of major response to treatment (TIS) in DM-1 shows potential for achieving drug-free remission in patients with refractory myositis

*As of Jan 8, 2025.
CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity; CK, creatinine kinase; HCQ, hydroxychloroquine; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; TIS, total improvement score; U/L, units per liter.
Cabaletta Bio: Data on file.

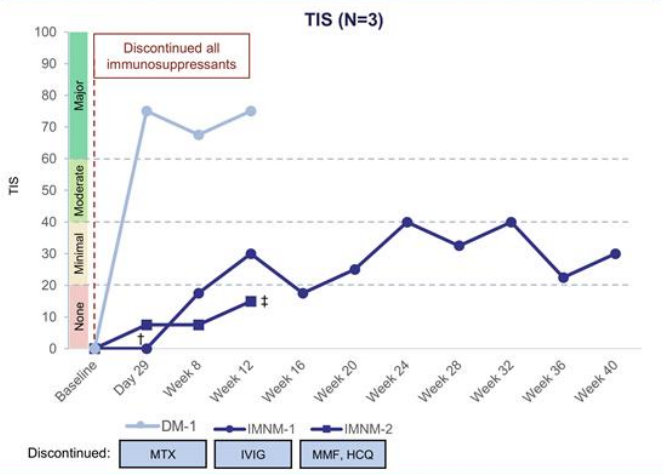
RESET-Myositis™: Efficacy data following rese-cel infusion[1]

1st IMNM patient with longer follow up demonstrated continuing clinical response off immunosuppressants*

Disease activity & improvement measures



1st IMNM patient demonstrated continuing clinical response off immunosuppressants without flares at Week 40



Initial clinical responses in IMNM are consistent with published data;[2] response kinetics seem to differ among myositis subtypes

*As of Jan 8, 2025. †IMNM-1 Day 29 CK measurement was unavailable; Day 22 used. ‡IMNM-2 developed a PE at Day 38 with a prolonged hospitalization and recovery and received IVIG just after Week 12 visit and increased prednisone from 5 mg to 20 mg 2 weeks later. CK, creatinine kinase; HCQ, hydroxychloroquine; IVIG, intravenous immunoglobulin; MTX, methotrexate; MMF, mycophenolate mofetil; MMT-8, manual muscle testing 8; TIS, total improvement score; U/L, units per liter.

1. Cabaletta Bio: Data on file. 2. Schett, G. 'CAR-T Cell Therapy: "The Future is Now."' 5th Global Conference on Myositis. iMyoS. Pittsburgh, PA.

Cabaletta Bio®

RESET-SLE™: Efficacy data following rese-cel infusion*

3 out of 4 SLE patients have achieved DORIS remission and 1st LN patient achieved CRR off all IS and steroids

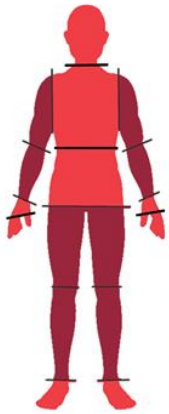
	SLE				LN	
Patient	**SLE-1†**	**SLE-2**	**SLE-3**	**SLE-4**	**LN-1**	**LN-2**
Latest follow-up (weeks)	36	16	8	8	24	4
DORIS remission (at latest follow-up)	–	✓	✓	✓	–	–
LLDAS (at latest follow-up)	–	✓	✓	✓	✓	–
SLEDAI-2K score‡ (baseline to latest follow-up)	26⟶8	10⟶0	8⟶2	8⟶2	22⟶2	14⟶11
Urine protein-creatinine ratio (baseline to latest follow-up)	1.08⟶0.55	N/A	N/A	N/A	7.22⟶0.45	4.85⟶2.56
Complete renal response (at latest follow-up)	–	N/A	N/A	N/A	✓	–
Glucocorticoid-free#	✓	✓	✓	✓	✓	✓
Immunosuppressant-free	✓	✓	✓	✓	✓	✓

*As of Jan 8, 2025
† Enrollment in the LN cohort requires class III/IV +/- V LN. SLE-1 had isolated class V LN and extra-renal SLE disease activity that met inclusion criteria for the non-renal cohort. Proteinuria contributed 4 SLEDAI-2K points at all assessments.
‡ SLEDAI-2K components at latest follow up: SLE-1: proteinuria-4, complement-2, dsDNA-2; SLE-3: dsDNA-2; SLE-4: dsDNA-2; LN-1: rash-2; LN-2: proteinuria-4, leukopenia-1, alopecia-2, complement-2, dsDNA-2
# SLE-4 and LN-1 had discontinued GC as of the data cut; as of the latest follow up SLE-4 was on 2.5mg/d of prednisone (week 8) and LN-1 was on 7mg/d of prednisone (week 24)
CRR, complete renal response; DORIS, definition of remission in SLE; IS, immunosuppressant; LLDAS, lupus low disease activity state; N/A, not applicable; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.
Cabaletta Bio: Data on file

RESET-SSc™: efficacy data in first SSc patient post rese-cel infusion[1]

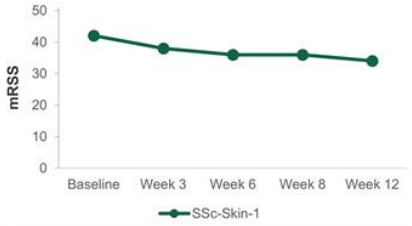
Improvements in skin across multiple body areas and in lung function, after discontinuing immunosuppressants*

Baseline mRSS score by body area[1]



0 None
1 Mild
2 Moderate
3 Severe

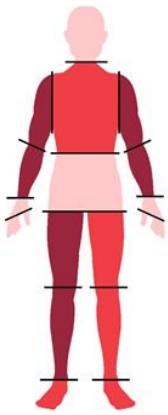
Overall mRSS score[1]



Pulmonary function tests

	Baseline	Week 12
DLCO	70%	85%
FVC	91%	97%

Week 12 mRSS score by body area[1]



0 None
1 Mild
2 Moderate
3 Severe

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

*As of Jan 8, 2025 patient is not taking immunosuppressants or steroids.
DLCO, % predicted diffusing capacity for carbon monoxide; FVC, % predicted forced vital capacity; mRSS, modified Rodnan Skin Score (measure of skin thickness in SSc across 17 body areas, with a maximum score of 51. Used as an outcome measure in SSc clinical trials as a surrogate for disease activity, severity, and mortality)[2].
1. Cabaletta Bio: Data on file. 2. Khanna D, et al. J Scleroderma Relat Disord. 2017;2(1):11–18.

Cabaletta Bio®

Securing & expanding our leadership in autoimmune cell therapy

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

Product/Process Innovations in development

- **Evaluating rese-cel in PV without preconditioning**
  - Published data and CAART platform experience 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 administration and follow-up**
- **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

Clinical Supply:

- Penn has reliably provided timely product for years
- WuXi partnership provides additional and expanded global rese-cel supply

Advancing Commercial-readiness Efforts:

- Commercial-ready drug product tech transfer process expected to be completed with Lonza as early as 2H25

Lonza

- Partnered with commercial supplier for vector

Oxford Biomedica

- Opportunity for additional manufacturing partners

Innovative Manufacturing:
Scale-Up, Reduce COGs & Improve Patient Experience

- Expanded partnerships for automated manufacturing
  - Completing Cellares technology assessment program

CELLARES

- 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

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FORTUNE BEST WORKPLACES IN BIOPHARMA 2024

Cabaletta's Anticipated Key Milestones for 2025

Cabaletta Bio®

Corporate Presentation

FEBRUARY 2025

Cabaletta Bio®

Cabaletta Bio Announces Updated Clinical Data Demonstrating Deepening Clinical Responses across Multiple Indications with Rese-cel at February Scientific Meetings

– Clinical efficacy continued to deepen over time with three SLE patients in DORIS remission, the first LN patient achieving complete renal response, and the first dermatomyositis patient maintaining a major TIS improvement; each of these patients discontinued all immunosuppressants and are off steroids as of the latest follow-up –

– Safety profile continues to suggest favorable risk-benefit in the first 10 patients dosed; 90% of patients experienced either no CRS or Grade 1 CRS (fever) and 90% of patients experienced no ICANS –

– Deep B cell depletion observed in all patients after rese-cel infusion with a transitional naïve B cell phenotype upon repopulation; tissue-resident B cell elimination confirmed by a lymph node biopsy in a scleroderma patient –

– 50 clinical sites in the U.S. and Europe actively recruiting with 26 patients enrolled across the RESET™ clinical development program as of February 13, 2025 –

PHILADELPHIA, Feb. 18, 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 new and updated clinical data from the first 10 patients dosed with resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) across the RESET clinical development program. These data were presented by Aimee Payne, M.D., Ph.D., Co-founder of and Scientific Advisory Board Co-chair at Cabaletta Bio in the 'Science Breakthroughs' session at the 2025 annual meeting of the American Association for the Advancement of Science, which was held in Boston, MA from February 13-15, 2025, and are being presented by Samik Basu, M.D., Chief Scientific Officer at Cabaletta Bio at the 5th International Conference on Lymphocyte Engineering, which is being held in Munich, Germany from February 20-22, 2025.

"The expanding clinical experience with rese-cel underscores its potential to provide compelling clinical responses without the need for immunosuppressants or steroids in patients with active, refractory autoimmune disease. With patients across the ongoing myositis, lupus and systemic sclerosis trials achieving DORIS remission in SLE, complete renal response in LN, and major TIS improvement in dermatomyositis, all while off all immunosuppressants and steroids, we believe rese-cel has the potential to transform the lives of patients with autoimmune disease," said David J. Chang, M.D., Chief Medical Officer of Cabaletta. "We intend to include these data when we meet with the FDA to align on registrational trial designs in the first half of 2025. We believe our expanding footprint of clinical sites in the US and Europe has facilitated our ability to accelerate the pace of enrollment and dosing across the RESET program. With an average of one patient enrolling per week since November, we anticipate that we will generate sufficient data to further clarify rese-cel's profile across multiple indications this year to rapidly deliver its therapeutic potential for autoimmune patients."

Cabaletta is currently evaluating rese-cel in the RESET (REstoring SElf-Tolerance) clinical development program, which includes six company-sponsored Phase 1/2 clinical trials with disease-specific cohorts, spanning the therapeutic areas of rheumatology, neurology and dermatology. All cohorts are evaluating a weight-based single infusion of rese-cel following a preconditioning regimen of fludarabine and cyclophosphamide, except for the RESET-PV™ trial, which is evaluating weight-based dosing of rese-cel without preconditioning.

New and Updated Clinical Data Summary

As of the data cut-off date of January 8, 2025, 10 patients had been dosed with rese-cel across the RESET-Myositis™, RESET-SLE™ and RESET-SSc™ trials with sufficient follow-up to be evaluable, providing the following key insights:

- In the RESET-Myositis trial, the first adult dermatomyositis patient maintained a major total improvement score (TIS) improvement at 3 months post-infusion, off all immunosuppressants and steroids, showing potential for achieving drug-free remission in patients with refractory myositis. In addition, initial clinical responses in the first 2 immune-mediated necrotizing myopathy (IMNM) patients continued to show more gradual improvement, consistent with published academic data, suggesting response kinetics may differ among myositis subtypes.
- In the RESET-SLE trial, 3 out of 4 patients in the non-renal systemic lupus erythematosus (SLE) cohort achieved DORIS (definition of remission in SLE) remission as of the most recent follow-up visit. The first patient dosed with rese-cel in the lupus nephritis (LN) cohort achieved a complete renal response (CRR). All 6 SLE and LN patients dosed, including these patients, demonstrated clinical responses off all immunosuppressants and steroids as of the data cut-off date.
- In the RESET-SSc trial, the first patient dosed with rese-cel in the severe skin cohort continued to demonstrate clinically meaningful skin improvements across an increasing number of body areas at 3 months post-infusion, in addition to improvement in lung function, after discontinuing all disease-specific therapies.
- Rese-cel consistently demonstrated deep depletion of B cells in the periphery within the first month of infusion. Tissue resident depletion consistent with the deep B cell depletion in circulation was confirmed by a lymph node biopsy in a systemic sclerosis patient. B cell repopulation has typically started around 2 months post-infusion and exhibited a transitional naïve phenotype, reflecting the production of new B cells after deep systemic depletion.
- Across the first 10 patients dosed with rese-cel with at least one month offollow-up, 90% experienced either no cytokine release syndrome (CRS) or grade 1 CRS (fever) and 90% experienced no immune effector cell-associated neurotoxicity syndrome.

Additional information can be accessed on the website of each scientific meeting. Presentation materials will be made available on the Posters & Publications section of the Company’s website following each event.

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 deeply deplete all CD19-positive cells in both the peripheral circulation and within tissues. This approach has the potential to reset the immune system and result in profound 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 expanding 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 with a single weight-based dosing regimen across 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 profound 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 belief that its expanding clinical experience with rese-cel underscores its potential to provide compelling clinical responses without the need for immunosuppressants or steroids in patients with active, refractory autoimmune disease, as well as its belief that rese-cel has the potential to transform the disease outcome and the lives of patients with autoimmune disease; and Cabaletta's belief that its growing number of sites will allow it to continue accelerating the pace of enrollment and dosing across the RESET program, further enabling it to evaluate the emerging clinical profile of rese-cel and its therapeutic potential for autoimmune patients.

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.

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com