
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 23, 2026

CABALETTA BIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

2929 Arch Street
Suite 600
Philadelphia, Pennsylvania
(Address of Principal Executive Offices)

001-39103
(Commission File Number)

82-1685768
(IRS Employer
Identification No.)

19104
(Zip Code)

Registrant's Telephone Number, Including Area Code: (267) 759-3100

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 March 23, 2026, Cabaletta Bio, Inc. (the "Company") announced its financial results for the fourth quarter and fiscal year ended December 31, 2025. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

On March 23, 2026, the Company posted to the "Investors & Media" section of the Company's website at www.cabalettabio.com an updated corporate presentation (the "Corporate Presentation"). A copy of the Corporate Presentation is attached hereto as Exhibit 99.2 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in Item 2.02 and 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 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 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

- 99.1 [Press Release issued by the registrant on March 23, 2026, furnished herewith.](#)
 - 99.2 [Cabaletta Bio, Inc. Corporate Presentation, dated March 2026, furnished herewith.](#)
 - 104 Cover Page Interactive Data File (embedded within the Inline XBRL Document).
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SIGNATURE

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

CABALETTA BIO, INC.

Date: March 23, 2026

By: /s/ Steven Nichtberger
Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)



Cabaletta Bio Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

Rese-cel myositis BLA submission on track for 2027 based on a 17-patient, single arm registrational cohort design, including an outpatient dosing option

No-preconditioning program enrolling in lupus and PV; anticipating initial RESET-SLE™ data in 1H26 and durability data from the RESET-SLE and RESET-PV® trials throughout 2026

Automated manufacturing of rese-cel with Cellares' Cell Shuttle™ underway in the RESET™ clinical program, offering the potential to produce rese-cel for thousands of patients per year with minimal capital investment

Pivotal trial designs announced for SLE and LN single arm cohorts, each with ~25 patients; on track to announce SSc design in 1H26; FDA registrational design discussions and no preconditioning data will inform pivotal plans across the rese-cel program

Complete Phase 1/2 data to be presented in 1H26 from the RESET-SSc™, RESET-SLE and RESET-MG™ trials evaluating rese-cel with preconditioning

PHILADELPHIA, March 23, 2026 -- Cabaletta Bio, Inc. (Nasdaq: CABA), a late-stage clinical biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases, today reported financial results for the fourth quarter and full year ended December 31, 2025, and provided a business update.

"As we advance our core clinical programs for rese-cel with preconditioning and standard manufacturing, we have meaningfully advanced two potentially transformative innovations: rese-cel with no preconditioning and automated manufacturing using the Cellares Cell Shuttle. Clinical data on both innovations are on track to be shared in the first half of this year with durability data to follow later this year. Clinical data currently suggest that rese-cel offers a competitive profile that may reliably deliver an immune reset following a single, weight-based infusion with a safety profile that facilitates outpatient delivery with – or potentially without – preconditioning," said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta.

Recent Operational Highlights and Upcoming Anticipated Milestones

Rese-cel: Rese-cel (rescabtagene autoleucel) is an investigational, autologous CAR T cell therapy engineered with a fully human CD19 binder and a 4-1BB co-stimulatory domain, designed specifically for the treatment of autoimmune diseases. Administered as a single, weight-based infusion, rese-cel has demonstrated the ability to transiently, reliably and deeply deplete CD19-positive cells, with the goal of resetting the immune system and achieving durable clinical responses without the need for chronic therapy. Cabaletta is evaluating rese-cel in the RESET™ (REstoring SElf-Tolerance) clinical development program, which includes multiple

ongoing company-sponsored trials across a broad range of autoimmune diseases in rheumatology, neurology and dermatology.

- **Registrational DM/ASyS cohort in RESET-Myositis[®] enrolling with outpatient dosing option:** The registrational dermatomyositis (DM) and antisynthetase syndrome (ASyS) cohort is enrolling and is expected to evaluate 17 patients with a 16-week primary endpoint of moderate or major total improvement score response while off immunomodulators and on no or low-dose steroids. If successful, data from this cohort will support Cabaletta's first projected Biologics License Application (BLA) submission for rese-cel in myositis in 2027.
 - **First clinical experience using automated Cellares manufacturing platform expected in 1H26:** Cabaletta anticipates reporting the initial clinical experience with rese-cel manufactured by Cellares in 1H26. The initial clinical experience is intended to confirm current Good Manufacturing Practice (GMP) readiness, including supply chain logistics, for Cellares-produced rese-cel implementation across the rese-cel portfolio. Longer-term clinical data from patients receiving rese-cel manufactured by Cellares are expected in 2H26. If successful, the Cellares Integrated Development and Manufacturing Organization (IDMO) Smart Factory has the potential to enable scalability to produce rese-cel for thousands of patients per year with minimal capital investment, lower manufacturing costs through decreased labor requirements with improved scheduling flexibility after commercialization and rapid expansion to global capacity. Cabaletta continues to work with its existing manufacturing partners to support the myositis registrational trial and launch-readiness efforts for rese-cel.
 - **No-preconditioning program advancing in RESET-SLE and RESET-PV:** Clinical data from patients treated with a single weight-based dose of rese-cel with no preconditioning are expected from the RESET-SLE trial in 1H26 (initial data) and 2H26 (durability data). Additionally, dose-ranging durability data from the RESET-PV trial are anticipated throughout 2026, supplementing the initial low dose PV data without preconditioning that were previously presented.
 - **Recent *Nature Biotechnology* publication and company presentation at the 2025 ASH Annual Meeting highlight rese-cel safety data across autoimmune portfolio:** A recent *Nature Biotechnology* review, which included rese-cel clinical data, highlighted that CAR T administration in autoimmune diseases has shown a more favorable safety profile when compared to its use in the oncology setting. In addition, Cabaletta's presentation at the 2025 ASH Annual Meeting expanded on these data, showing that in the first 40 patients treated with rese-cel with preconditioning, 95% of patients had either no cytokine release syndrome (CRS) or Grade 1 CRS and 95% of patients experienced no immune effector cell-associated neurotoxicity syndrome.
 - **Complete Phase 1/2 data anticipated from three RESET trials to be presented in 1H26:** Complete Phase 1/2 clinical data from cohorts in RESET-SLE, RESET-SSc and RESET-MG are expected to be presented in 1H26. In RESET-MG, data will be presented in an oral presentation at 1:24 p.m. CDT on Monday, April 20, 2026, at the American Academy of Neurology (AAN) Annual Meeting in Chicago, IL. Complete Phase 1/2 clinical data from cohorts in RESET-SLE and RESET-SSc are also expected in 1H26. These clinical data are expected to support Cabaletta's discussions with the FDA on potential registrational pathways specifically in RESET-SSc and RESET-MG.
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Cabaletta anticipates providing an update regarding registrational designs for RESET-SSc in 1H26 and for RESET-MG in mid-2026.

Fourth Quarter and Full Year 2025 Financial Results

- Research and development expenses were \$36.2 million and \$142.7 million for the three months and full year ended December 31, 2025, respectively, compared to \$25.5 million and \$97.2 million for the three months and full year ended December 31, 2024, respectively.
- General and administrative expenses were \$6.4 million and \$29.6 million for the three months and full year ended December 31, 2025, respectively, compared to \$8.3 million and \$27.9 million for the three months and full year ended December 31, 2024, respectively.
- As of December 31, 2025, Cabaletta had cash, cash equivalents and short-term investments of \$133.6 million, compared to \$164.0 million as of December 31, 2024. Since December 31, 2025, the Company has raised an additional \$30.0 million from a combination of ATM sales and exercise of certain common stock warrants set to expire in September 2026. The Company expects that its cash position as of December 31, 2025, along with cash raised during the first quarter of 2026, will enable it to fund its operating plan into the fourth quarter of 2026.

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a late-stage clinical 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 the FDA, including review of safety information from Cabaletta's ongoing clinical trials and discussions with the FDA on potential registrational pathways for rese-cel, including the timing of

registrational designs related thereto; Cabaletta's ability to leverage its emerging clinical data and its efficient development strategy; Cabaletta's belief that it has meaningfully advanced two potentially transformative innovations; Cabaletta's expectation around its clinical data that suggests that rese-cel can reliably deliver an immune reset following a single weight-based infusion with a safety profile that facilitates outpatient delivery with or potentially without preconditioning; Cabaletta's ability to capitalize on and potential benefits resulting from its research and translational insights; the clinical significance of the clinical data read-out at upcoming scientific meetings and timing thereof; Cabaletta's expectations around the potential success and therapeutic benefits of rese-cel; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel in patients with SLE, myositis, SSc, gMG and PV and advancement RESET-MS trial, including updates related to status, enrollment, safety data, efficiency of clinical trial design and timing of initial data and durability data read-outs or otherwise; Cabaletta's plans of discussions with the FDA on registrational cohort designs and timing thereof; Cabaletta's plans to announce additional clinical data from the RESET trials throughout 2026, including complete Phase 1/2 data to be presented in 1H26 from the RESET-SSc, RESET-SLE and RESET-MG trials evaluating rese-cel with preconditioning; Cabaletta's expectations that the additional clinical data from the RESET trials will inform discussions with the FDA regarding registrational cohort designs for rese-cel in various indications; Cabaletta's plans to submit a BLA for rese-cel in myositis in 2027 and obtain regulatory approval from the FDA and other regulatory authorities; Cabaletta's plans to implement automated manufacturing of rese-cel with Cellares' Cell Shuttle, including timing of initial clinical experience and durability data and its expectation that it can enable scalability to treat thousands of patients per year with minimal capital investment; and Cabaletta's use of capital, expense and other financial results in the future and its ability to fund operations into the fourth quarter 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 results from one program may not translate to results for another program; 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.

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

Statements of Operations

	<u>Three months ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2025</u>	<u>2024</u>	<u>2025</u>	<u>2024</u>
	<u>Unaudited</u>			
Operating expenses:				
Research and development	\$ 36,194	\$ 25,532	\$ 142,674	\$ 97,203
General and administrative	6,417	8,253	29,567	27,938
Total operating expenses	42,611	33,785	172,241	125,141
Loss from operations	(42,611)	(33,785)	(172,241)	(125,141)
Interest income	1,326	1,947	6,031	10,025
Interest expense	(555)	(748)	(2,004)	(748)
Other income, net	(79)	—	358	—
Net loss	<u>\$ (41,919)</u>	<u>\$ (32,586)</u>	<u>\$ (167,856)</u>	<u>\$ (115,864)</u>
Net loss per voting and non-voting share, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.65)</u>	<u>\$ (2.10)</u>	<u>\$ (2.34)</u>

Selected Balance Sheet Data

	<u>December 31,</u>	
	<u>2025</u>	<u>2024</u>
	<u>Unaudited</u>	
Cash, cash equivalents and short-term investments	\$ 133,599	\$ 163,962
Total assets	165,083	185,046
Total liabilities	53,032	32,711
Total stockholders' equity	112,051	152,335

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

Cabaletta Bio[®]

Corporate Presentation

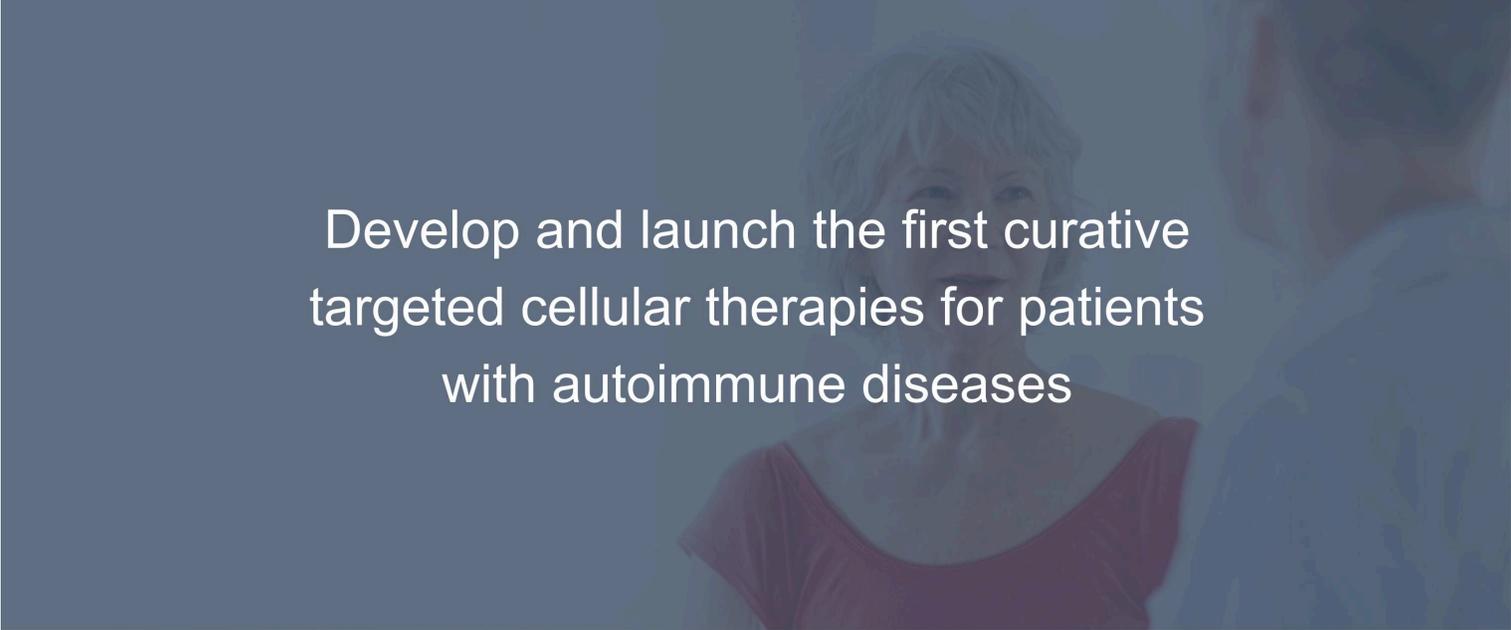
MARCH 2026

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Disclaimer

This 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 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 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 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, 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 timing, clinical significance and impact of clinical data read-outs, including the progress, results and clinical data from each of the patients dosed with rese-cel in the Phase 1/2 RESET-Myositis, RESET-SLE, RESET-SSc, RESET-MG and RESET-PV trials and our other planned activities with respect to rese-cel; our belief that rese-cel has the potential to provide drug-free, durable transformative clinical responses, through an immune reset; the Company's advancement of separate Phase 1/2 clinical trials of rese-cel and advancement of the RESET-PV and RESET-MS trials, with and without preconditioning, as applicable, 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 and interactions with regulatory authorities, including such authorities' review of safety information from our ongoing clinical trials and discussions with regulatory agencies on potential registration pathway for rese-cel in various indications, and the timing of trial design related thereto; our ability to successfully complete our preclinical and clinical studies for our product candidates, including our ability to progress the trial; our plans and expectations regarding automated scalable manufacturing and no preconditioning and its potential to expand and accelerate access; our expectations that automation and elimination of preconditioning and apheresis will enhance patient experience; our expectation and timing for clinical manufacturing data with Cellares' automated manufacturing process and its ability to confirm GMP readiness, including supply chain logistics, as well as its potential to provide scalability for thousands of patients per year and to facilitate post-approval expansion; 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 regulatory designations and the anticipated initiation of registration cohorts and potential BLA submission; our expectation and timing for completion of dosing of most disease-specific cohorts; our expectations regarding opportunities based on market research; our ability to accelerate our pipeline to approval and launch and to develop transformative therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on, including timing thereof, our development programs; our ability to contract with third-party suppliers and manufacturers; 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; our expectations regarding the potential commercial and economic benefits of preconditioning elimination and automated manufacturing, including its potential to reduce costs of goods, minimize capital investment requirements, and support efficient global expansion of rese-cel. 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 development activities and clinical trials, risks related to our ability to demonstrate sufficient evidence of safety, efficacy and tolerability in our clinical trials, the risk that the results observed with the similarly-designed construct, including, but not limited 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, risks related to clinical trial site activation or enrollment rates that are lower than expected, 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 regulatory 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, risks related to volatile market and economic conditions and our ability to fund operations and continue as a going concern. 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 and quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our other 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.



Develop and launch the first curative
targeted cellular therapies for patients
with autoimmune diseases

Cabaletta Bio[®]

Rese-cel¹: Delivering on the promise of CD19-CAR T in autoimmunity

Pivotal myositis study enrolling; automated manufacturing & new clinical data with no preconditioning in 2026

- **Autologous CAR T has delivered reliable, durable, transformative outcomes for autoimmune patients²**
 - Rese-cel data: immunomodulator-free efficacy with a favorable safety profile using a single weight-based dose
 - Complete phase 1/2 data expected in systemic sclerosis, lupus & myasthenia gravis in 1H26
- **Myositis: 17 patient single-arm study with planned 2027 BLA submission including potential for outpatient infusion**
 - Primary endpoint: moderate TIS off immunomodulators & on no or low dose steroids³ at 16 weeks
 - All phase 1/2 patients with sufficient f/u who would have met inclusion criteria met the registrational primary endpoint⁴
- **Safety profile in first 40 patients dosed with preconditioning (PC) supports outpatient administration⁴**
 - 95% - No CRS (~67%) or Grade 1 CRS (~28% - fever); 95% - No ICANS⁵
- **Automated manufacturing by Cellares offers potential scale to thousands of patients with minimal capital investment**
 - IND amendment cleared for automated, scalable manufacturing of rese-cel based on multiple engineering runs
- **No preconditioning: low dose cohort with early near-complete symptom resolution in 2/3 autoimmune patients^{4,6}**
 - Dose-ranging data in RESET-SLE and RESET-PV anticipated throughout 2026

**Safety profile of rese-cel in autoimmune patients supports outpatient use;
Automated scalable manufacturing and no preconditioning can expand & accelerate access**

BLA – biologics license application; f/u – follow-up; PV – pemphigus vulgaris; SLE – systemic lupus erythematosus; TIS – total improvement score.

1. resecabtagene autoleucel; CABA-201

2. Solimani, Farzan, et al. "Clinical progress of engineered cellular immunotherapies for autoimmunity." Nature Biotechnology (2026): 1-16.

3. Low dose steroids is defined as 50% reduction from baseline or ≤ 7.5 mg/day.

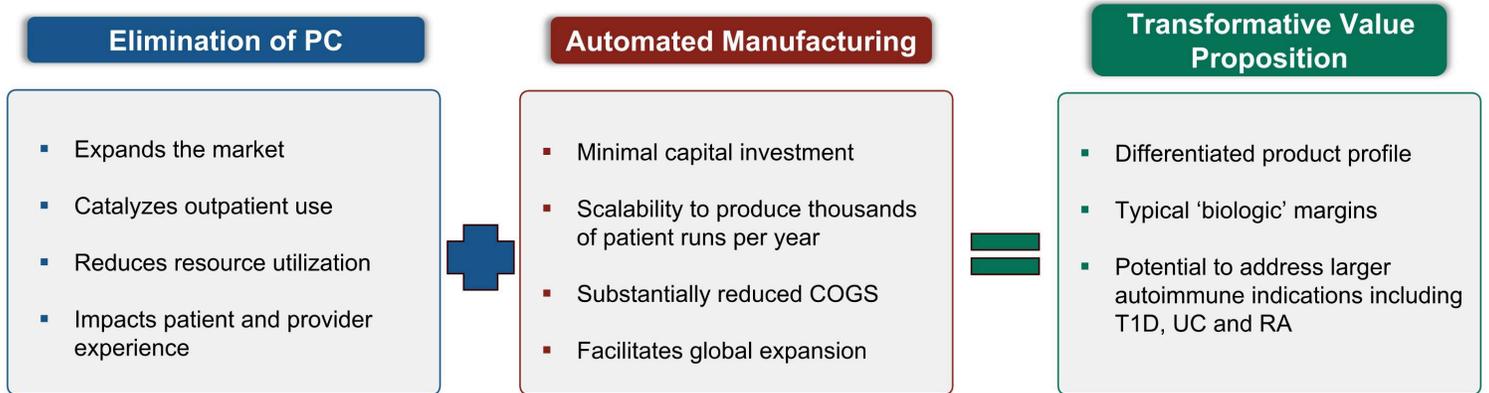
4. As of data cut-off on September 11, 2025.

5. As of data cut-off on October 30, 2025

6. Basu, S. RESET-PV: Initial clinical and translational data evaluating rese-cel without preconditioning in pemphigus vulgaris. Presented at ESGCT 2025; October 6-10, 2025; Seville, Spain.

Transformative value proposition with PC elimination & automation

Removing PC should expand access while automated manufacturing should reduce COGS & increase scale



1H26

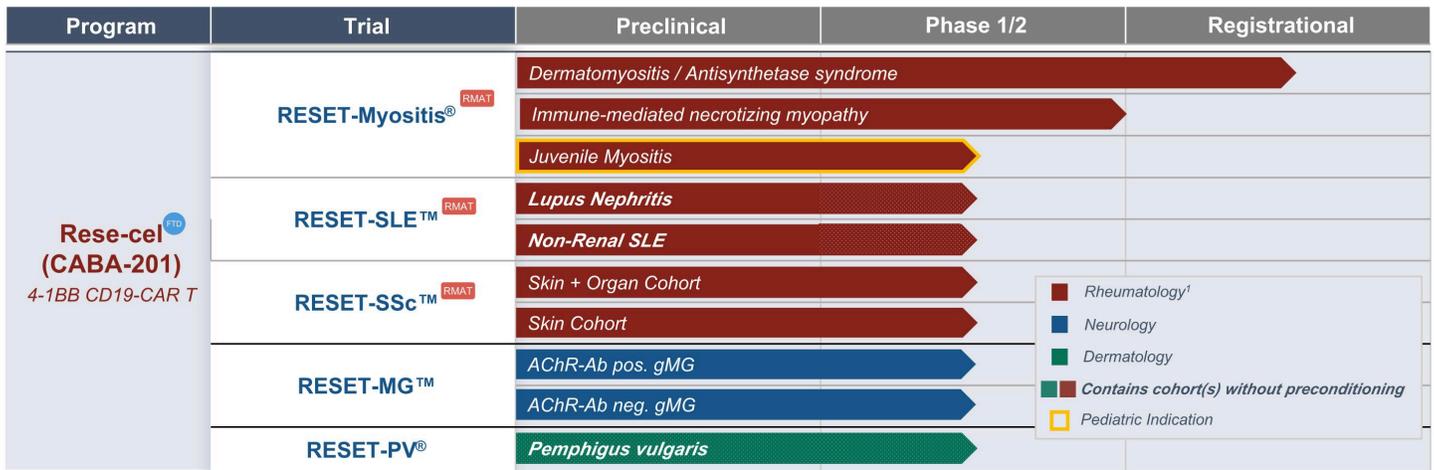
*Initial clinical data without PC from the first SLE cohort
and initial clinical experience with rese-cel manufactured by Cellares*

2H26

*Durability data without PC from the SLE & PV dose cohorts
and longer-term data from patients receiving rese-cel manufactured by Cellares*

Innovative clinical strategy to support accelerated regulatory path

SLE registrational design in hand; SSc pivotal design anticipated 1H26 and MG anticipated mid-2026



1H26

Complete Phase 1/2 data expected in SLE/LN, SSc and MG

RESET[™] – REstoring SElf-Tolerance; Ab – Antibody; AChR – Acetylcholine receptor; gMG – Generalized myasthenia gravis; PV – Pemphigus vulgaris; SLE – Systemic lupus erythematosus; SSc – Systemic sclerosis

¹ Myositis patients can also be treated by neurologists or dermatologists; lupus nephritis patients can also be treated by nephrologists.

● FDA Fast Track Designation received in dermatomyositis, SLE and lupus nephritis, systemic sclerosis, generalized myasthenia gravis and multiple sclerosis.

■ FDA Regenerative Medicine Advanced Therapy (RMAT) received in myositis, SLE, LN and systemic sclerosis.



Rese-cel:
Clinical Profile and Commercial Opportunity

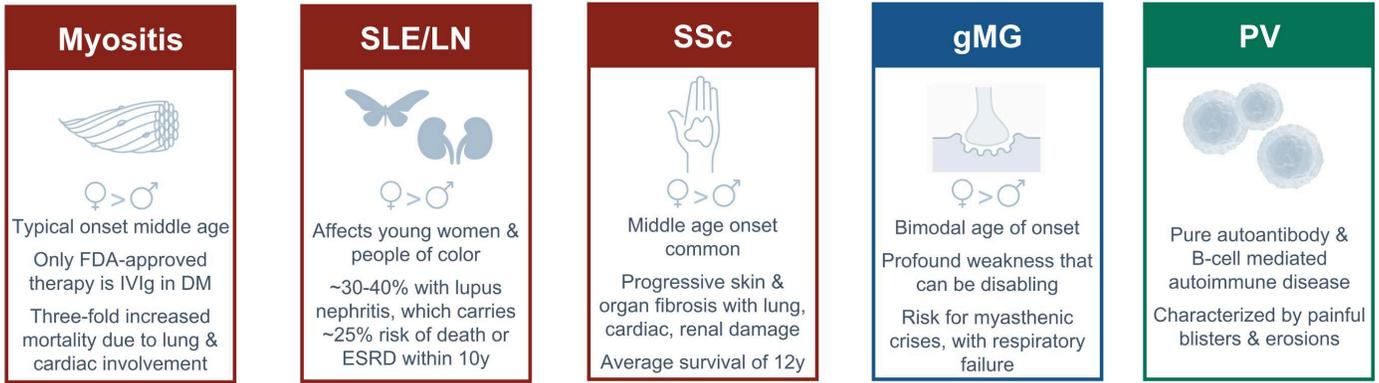
Cabaletta Bio[®]

RESET™ program advancing trials in a broad portfolio of diseases

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

— No PC Cohorts —

— No PC only —



U.S. Prevalence



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

Cabaletta Bio®

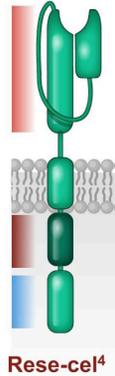
Rese-cel: CD19-CAR T specifically designed for autoimmunity

Rese-cel binder with similar *in vitro* & *in vivo* activity to construct used in academic studies in autoimmunity^{1,3}

Fully human anti-CD19 binder

4-1BB costimulatory domain

CD3- ζ signaling domain



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 clinical and translational data⁵
- ▶ Patients treated with rese-cel have shown compelling clinical responses with safety data that supports outpatient use for autoimmune patients⁶

1. Peng BJ, et al. Mol Ther Methods Clin Dev. 2024;32(2):101267.

2. Dai, Zhenyu, et al. "Development and functional characterization of novel fully human antiCD19 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)

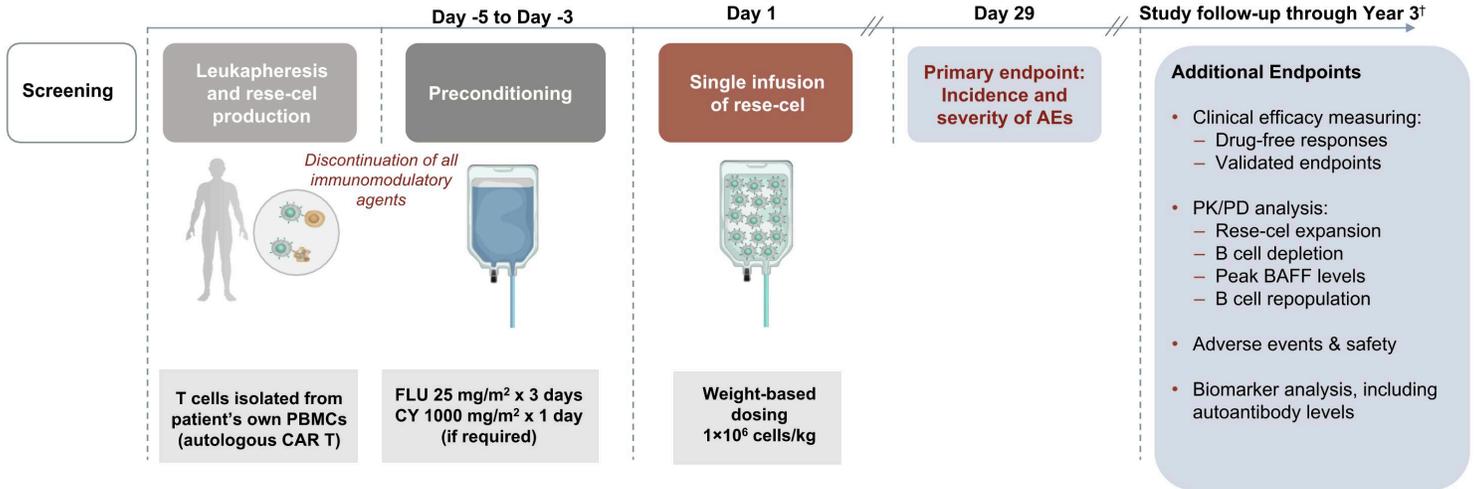
Transmembrane domain in rese-cel is CD8 α vs. TNFRSF19 (Troy) utilized in the academic construct. The two transmembrane domains have not been shown to have a significant difference in function or IFN γ production in preclinical studies. The CD8 α transmembrane domain is employed in tisagenlecleucel.

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™ clinical trials have consistent design principles¹

Many of the RESET trials share common elements of preconditioning, dose, and study design



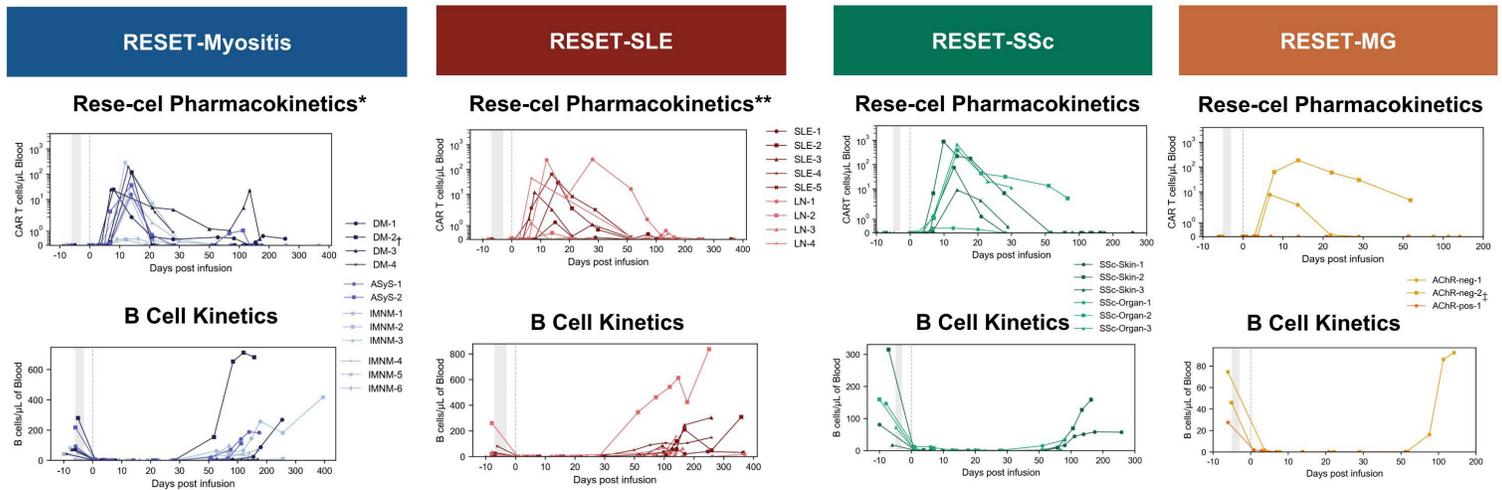
[†]Follow up period encompasses at least 15 years in total, ed to regulatory guidance for CAR T cell therapies.

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 SEIf-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.

Rese-cel expansion & B cell kinetics across indications*

Peak rese-cel expansion and transient peripheral B cell depletion occurred within ~2 weeks post infusion



Peripheral B cells begin repopulating ~2 to 3 months after rese-cel in patients with sufficient follow-up*

*All data is as of 11 Sep, 2025, except DM-3 which includes Week 24 data as of 08 Oct 2025.

**LN-1 had prolonged rese-cel detection due to TCR activation that corresponded to longer time to B cell repopulation. LN-4: follow up ongoing

† DM-3 rese-cel PK at Week 20 was artifactually elevated due to low circulating lymphocyte counts.

‡ Reduced rese-cel expansion observed in ACHR-pos-1 may be attributed to patient's continued use of azathioprine, a prohibited medication, until day of infusion (Day 1).

ASyS, antisynthelase syndrome; CAR, chimeric antigen receptor; DM, dermatomyositis; IMNM, immune-mediated necrotizing myopathy; LN, lupus nephritis; rese-cel, resecabtagene autoleucel; RESET,

REStoring SEIf-Tolerance; SLE, systemic lupus erythematosus, SSc, systemic sclerosis, TCR, T cell receptor.

Cabaletta Bio: Data on file.

Demographics & CRS/ICANS in 1st 40 rese-cel patients by indication

Across 4 RESET™ studies, 95% of patients with no CRS or Grade 1 CRS (fever) and 95% with no ICANS¹

Baseline characteristics of autoimmune disease patients treated with rese-cel

	RESET-Myositis	RESET-SLE	RESET-SSc	RESET-MG
Number of patients	15	10	9	6
Age, years, mean (SD)	51.7 (14.6)	30.4 (7.6)	53.1 (12.3)	57.5 (9.8)
Sex, % female	53.3	80.0	66.7	66.7
Duration of disease, years, mean (SD)	5.4 (3.7)	9.8 (5.0)	2.2 (1.3)	5.1 (5.3)

Incidence, severity and onset of CRS and ICANS in the 1st 28 days in patients treated with rese-cel

	RESET-Myositis	RESET-SLE	RESET-SSc	RESET-MG	Total
CRS [‡] , n (%)	5 (33.3)	3 (30.0)	4 (44.4)	1 (16.7)	13 (32.5% CRS)
CRS Grade 1, n (%)	5 (33.3)	3 (30.0)	3 (33.3)	0 (0.0)	11 (27.5% G1 CRS)
CRS Grade 2, n (%)	–	–	1 (11.1)	1 (16.7)	2 (5% G2 CRS)
Time to CRS onset, days [§] (mean)	7.4	7.3	8.5	7.0	7.7 days
CRS duration [†] , days (mean)	4.6	3.0	3.0	2.0	3.5 days
ICANS [‡] n (%) (Grade)	–	1 (10) (G4)	1 (11.1) (G3)	–	2 (5% ICANS)
Time to ICANS onset, days (mean)	–	9.0	8.0	–	8.5 days
ICANS duration, days (mean)	–	3.0	3.0	–	3.0 days

[‡]Days relative to rese-cel infusion.

[†]Events occurring within 7 days of each other are considered as 1 episode. IMNM-3 CRS duration includes preceding event of fever which was consistent with CRS definition.

[‡]Graded per ASTCT Consensus Grading Criteria.

[§]Presented at ASH 2025 with data cut-off as of October 30, 2025.

CAR T may eliminate active disease & use of expensive medications

Rese-cel safety profile permits outpatient administration which can facilitate favorable reimbursement

✘ Cancer CAR T: Safety profile often requires inpatient infusion, affecting reimbursement

Cancer patients experience early and frequent CRS/ICANS following CAR T therapy, which increases inpatient admissions and shifts Medicare reimbursement to the DRG system.

Majority of oncology patients treated with CAR T therapy experience CRS within first 5 days post-infusion¹

Many cancer patients are insured under Medicare, which has inpatient **DRG-018** reimbursement

✔ Rese-cel: Safety profile facilitates outpatient infusion, which can favorably impact reimbursement

Commercial

Myositis & SSc patients often commercially insured (60%-75%)^{2,3}



CRS less frequent & severe, delayed onset → potential outpatient administration



Outpatient CAR T infrastructure exists at many centers

Medicare

Outpatient administration supports viable Part B Medicare payments



RESETE clinical site footprint can be leveraged to generate early adopters

1. Ferreri, Christopher J., and Manisha Bhutani. "Mechanisms and management of CAR T toxicity." *Frontiers in Oncology* 14 (2024): 1396490.

2. Smoyer-Tomic KE, et al. *BMC Musculoskelet. Disord.* 2012 Jun 15;13:103. doi: 10.1186/1471-2474-13-103.

3. Gale, Sara L., et al. "Characterizing disease manifestations and treatment patterns among adults with systemic sclerosis: a retrospective analysis of a US healthcare claims population." *Rheumatology and therapy* 7.1 (2020): 89-99.

RESET™ program designed for outpatient administration at launch

Outpatient administration reduces administrative burden and improves patient and provider accessibility



INPATIENT MODEL

Limited patient beds
and resource infrastructure

- ✗ Increases inpatient resource pressure:
↑ total cost of care, human resource
and bed space demands
- ✗ Reduces eligible patients treated



OUTPATIENT MODEL

More favorable safety profile
reduces need for inpatient admission

- ✓ Reduces use of hospital resources;
Increases throughput
- ✓ Reduces conflicts with cancer patient
use of in-patient beds

Rese-cel commercial model – manufacturing and COGM

Health status of patient population and slower disease progression improve manufacturing cost efficiency

✗ In oncology, disease progress & out of specification (OOS) rates increase costs and reduce margins

Late-stage oncology patients have high drop-off rate due to rapid disease progression and compromised T cell fitness, leading to higher manufacturing OOS rates^{1,2,3}

Increased OOS rates; ↑ COGM
+ ↓ revenue since out of spec
products not reimbursed

Disease progression reduces
revenue capture because
unused product not reimbursed

Reduced eligible patients,
resulting in economies of scale
not being achieved

Manufacturing capacity constraints
→ delayed commercial ramp-up

✓ In autoimmunity, healthier patients & fully automated rese-cel mfg, should support lower COGM



Autoimmune patients are not heavily pretreated with chemotherapy → more fit immune cells that support reliable manufacture, reducing COGM



Autoimmune patients rarely progress as rapidly as cancer patients → more reliable revenue realization for manufactured product



Building manufacturing capacity at CDMOs to support successful launch; Cellares automation has the potential to facilitate post-approval expansion

COGM – Cost of goods manufactured

1. U.S. Food and Drug Administration. Kymriah (tisagenlecleucel) Prescribing Information. Revised 2025, U.S. Food and Drug Administration <https://www.fda.gov/media/107296/download>
2. U.S. Food and Drug Administration. Breyanzi (lisocabtagene maraleucel) Prescribing Information. Revised 2025, U.S. Food and Drug Administration <https://www.fda.gov/media/145711/download>
3. U.S. Food and Drug Administration. Yescarta (axicabtagene ciloleucel) Prescribing Information. Revised 2025, U.S. Food and Drug Administration <https://www.fda.gov/media/108377/download>



Myositis: Unmet Need & Clinical Data

Cabaletta Bio[®]

Myositis: High rates of disability & increased risk of mortality

Highly concentrated treatment network in the US; dermatomyositis represents ~75% of this market

High disease burden: disability & mortality

- Typical patient is a middle-aged female who experiences muscle weakness, fatigue, pain, shortness of breath and difficulty swallowing
 - Moderate to severe disability (40% to 65%)¹
 - Assisted walking devices (18% to 38%)¹
- The **risk of mortality is ~3 times higher** than the general population, primarily due to cancer and lung & cardiac complications²
 - ~20% mortality < 5 years with standard immunosuppressive treatment³

"I find it **very difficult to get up from a regular chair**, I need boosters or assistance from somebody else. Walking, my **gait has really suffered**. My stability walking has suffered as well, and I **can't lift anything more than five or eight pounds**. So doing stuff is difficult. Bending down is very difficult. I **can't get up from the floor if I fall**."



"John"

61-year-old male with ASyS⁴
~10 yrs since diagnosis

"It just **affected every aspect of my life**. Just work, family, social life, own wellbeing. It just pours into everything else with that."



"Erica"

44-year-old female with DM⁴
~2.5 yrs since diagnosis

Subtype prevalence in the U.S.

~60,000 pts^{5,6}

Dermatomyositis (DM)

~15,000 pts^{7,8}

Anti-synthetase syndrome (ASyS)

~7,500 pts^{5,9}

Immune-mediated necrotizing myopathy (IMNM)

1. Opinc AH, Brzezinska OE, Makowska JS. Disability in idiopathic inflammatory myopathies: questionnaire-based study. Rheumatol Int. 2019;39(7):1213-1220.

2. Marie I. Morbidity and mortality in adult polymyositis and dermatomyositis. Curr Rheumatol Rep. 2012;14(3):275-285.

3. Schiopu E, Phillips K, MacDonald PM, Crofford LJ, Somers EC. Predictors of survival in a cohort of patients with polymyositis and dermatomyositis: effect of corticosteroids, methotrexate and azathioprine. Arthritis Res Ther. 2012;14(1):R22.

4. Primary market research conducted via third-party, blinded interviews with myositis patients, conducted in 2024.

5. Khoo 2023 6. Kronzer 2023 7. Coffey 2021 8. Dahal 2022 9. Shelley 2022

Myositis: Limited treatment options for ~80k U.S. patients

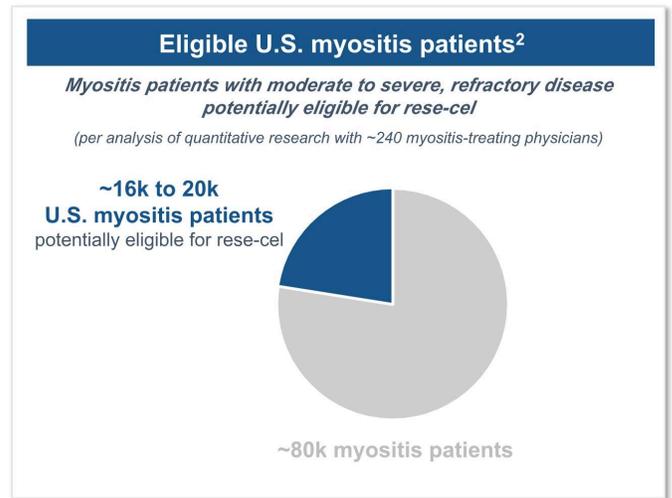
IVIg is the only approved therapy (only for patients with the adult dermatomyositis subtype)

> Autoimmune disease with B cells component

- Idiopathic inflammatory myopathies (IIMs, or myositis) are a group of autoimmune diseases characterized by inflammation and muscle weakness

> Limited treatment options¹

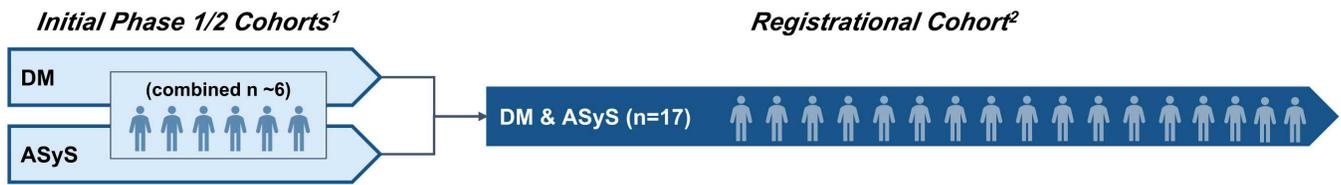
- Common therapies: steroids plus an immunomodulator (i.e. methotrexate, azathioprine, mycophenolate, rituximab)
- IVIg (intravenous immunoglobulin), the only FDA-approved therapy, is approved in adult dermatomyositis
- Therapies can carry potential long-term side effects such as serious infections and organ damage
- Despite existing therapies, disease is often refractory
- Two therapies in Phase 3 development, Brepocitinib and Vyvgart®, demonstrated improvement with chronic administration added onto existing immunomodulatory medications



1. Lundberg, Ingrid E., et al. "Idiopathic inflammatory myopathies." Nature Reviews Disease Primers 7.1 (2021): 86.
2. Analysis from quantitative survey of U.S. myositis-treating physicians, conducted 2Q25. N = ~240.

Myositis registrational cohort – Key design elements

Single-arm cohort including DM/ASyS patients with a primary endpoint at 16 weeks



- Expansion of current RESET-Myositis trial to include registrational cohort in DM / ASyS (~60k / ~15k US patients)
- Primary Endpoint:** Moderate or Major TIS response @ Week 16 off all immunomodulators and off or on low-dose³ steroids
- Expanded trial to 17 patients to ensure approximately 14 DM patients can enroll based on natural U.S. prevalence estimates
- Confirmed current dose of 1 million cells/kg in a single infusion
- Safety database ~100 autoimmune patients at ≥1-month of follow-up (with at least 35 myositis patients)
 - ~70% of the safety database already enrolled across the RESET clinical development program⁴

Registrational trial initiated with planned 2027 BLA submission

TIS, total improvement score.

1. Pediatric submission based on data available at the time of adult submission from ongoing Ph 1/2 study (no new study) to support pediatric label claim

2. Size of myositis registrational cohort based on key statistical parameters and estimated background remission rate in myositis.

3. Low dose steroids is defined as 50% reduction from baseline or ≤7.5 mg/day.

4. As of October 24, 2025.

Baseline characteristics: First 13 patients in RESET-Myositis*

All patients had active, refractory disease despite multiple immunomodulatory agents, including IVIg

	DM N=4	ASyS N=2	IMNM N=6	JIIM N=1
Mean age, years (min, max)	~58 (45, 72)	~44 (39, 48)	~55 (33, 64)	14
Female, n (%)	3 (75)	1 (50)	1 (17)	1 (100)
Years since diagnosis, mean (min, max)	3.0 (2.0, 3.6)	9.2 (3.6, 14.8)	4.5 (1.4, 8.8)	8.5
Myositis-specific autoantibody	50% TIF1- γ 25% NXP, 25% SAE	100% Jo-1	67% HMGCR 33% SRP	NXP-2
Baseline disease activity [†]				
Mean MMT-8	109.6	129.5	122.0	134.0
Median CK, U/L	40.0	311.5	2214.5	176.0
Mean CDASI-A	26	N/A	N/A	N/A
Prior RTX [‡]	75%	100%	50%	100%
Prior IVIg [‡]	100%	100%	83%	100%
Therapies at Screening				
Systemic GCs	75%	100%	67%	0
≤ 2 IMs	50%	50%	100%	0
≥ 3 IMs	50%	50%	0%	100%

*As of 11 Sep, 2025.

[†]Baseline disease activity = activity before preconditioning.

[‡]Reflects any exposure to RTX and IVIg prior or at time of study entry. RTX is not allowed within approximately 6 months of Screening.

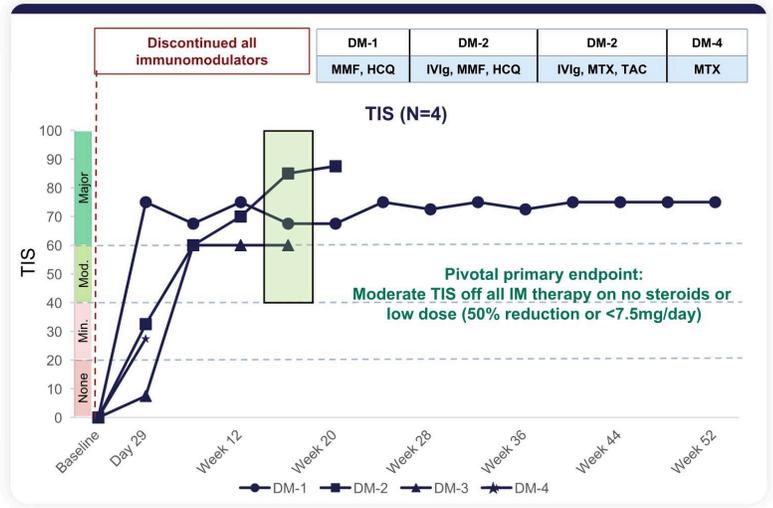
ASyS, antisynthetase syndrome; CDASI-A, Cutaneous Dermatomyositis Disease Area and Severity Index – Activity; CK, creatine kinase; DM, dermatomyositis; GC, glucocorticoid; HMGCR, 3-hydroxy-3-methylglutaryl-coenzyme A reductase; IM, immunomodulatory medication; IMNM, immune-mediated necrotizing myopathy; IVIg, intravenous immunoglobulin; JIIM, juvenile idiopathic inflammatory myopathy; MMT-8, manual muscle testing 8; NXP, nuclear matrix protein; N/A, not applicable; RESET, REStoring SElf-Tolerance; RTX, rituximab; SAE, small ubiquitin-like modifier activating enzyme; SRP, signal recognition particle; TIF1, transcription intermediary factor 1; U/L, units per liter.

Cabaletta Bio – Data on File.

DM: Efficacy data following rese-cel infusion*

3 of 3 patients with DM with sufficient follow-up achieved major TIS responses at Week 16

Assessment at Week 16	DM Patients (baseline autoantibody)			
	DM-1 (SAE)	DM-2 (None detected†)	DM-3 (TIF1-γ)	DM-4 (TIF1-γ)
IM-free	✓	✓	✓	✓ ‡
Low dose or no GC	✓	✓	✓	✓ ‡
TIS Response	Major	Major	Major	N/A§
Complete and transient B cell depletion	✓	✓	✓	✓ ‡
Antibody trend¶	↓	N/A	↓	N/A§
Meets pivotal primary endpoint	✓	✓	✓	N/A§



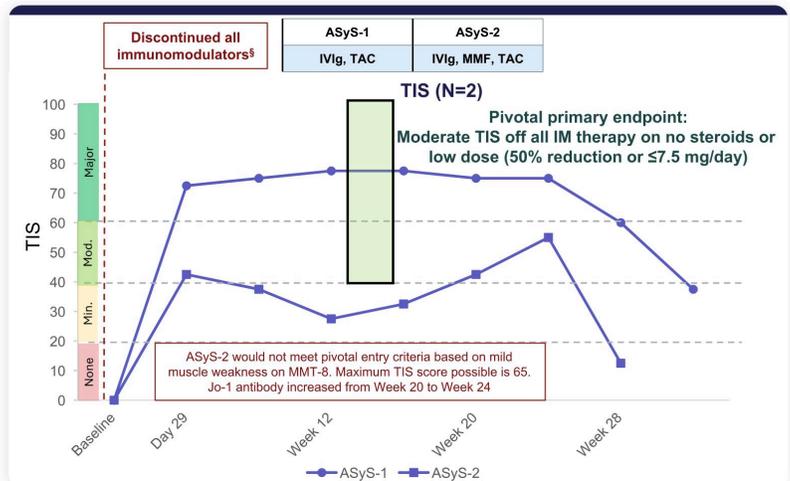
After discontinuation of all IM medications, 3 of 3 DM patients achieved the 16-week primary endpoint for the upcoming pivotal study of at least moderate TIS response

*As of 11 Sep, 2025.
 † Historical NXP-2 autoantibody, but none detected at Pre-preconditioning (Baseline visit). ‡ At latest follow-up (Day 29). § Insufficient follow-up. ¶ Reflects trend from baseline to latest timepoint.
 DM, dermatomyositis; FDA, Food and Drugs Administration; GC, glucocorticoids; HCQ, hydroxychloroquine; IM, immunomodulatory medication; IVIg, intravenous immunoglobulin; mg, milligrams; MMF, mycophenolate mofetil; MTX, methotrexate; N/A, not available; NXP, nuclear matrix protein; rese-cel, resecabtagene autoleucel; SAE, small ubiquitin-like modifier activating enzyme; TAC, tacrolimus; TIF1-γ, transcription intermediary factor 1 gamma; TIS, total improvement score.
 Cabaletta Bio: Data on File. Cabaletta Bio® 21

ASyS: Efficacy data following rese-cel infusion*

Patient who would meet key inclusion criteria in registrational cohort achieved a major TIS response at Week 16

Assessment at Week 16	ASyS (baseline autoantibody)	
	ASyS-1 (Jo-1)	ASyS-2 (Jo-1)
IM-free	✓	✓
Low dose or no GC	✓	✓
TIS response	Major	Minimal
Complete and transient B cells depletion	✓	✓
Antibody trend [†]	↓‡	↓ → ‡
Meets pivotal primary endpoint	✓	✗



Responses to CD19-CAR T among some ASyS patients may be time-limited by the recurrence or persistence of pathogenic autoantibodies¹⁻³ from CD19-negative long-lived plasma cells despite complete B cell depletion

*As of 11 Sep, 2025.

[†]Reflects trend from baseline to latest timepoint antibody results are available (Week 24 for both patients). In ASyS-2, Jo-1 antibody level trended up from Week 20 to Week 24 but was lower than baseline.

[‡]Based on the research-based, qualified, quantitative Luminex assay. §ASyS-1 to minimal response at latest follow-up (Week 32); treated with GC bursts and obinutuzumab; ASyS-2 to no response at latest follow-up (Week 28); treated with GC burst.

ASyS, antisynthetase syndrome; FDA, Food and Drugs Administration; GC, glucocorticoids; IM, immunomodulatory medication; IVIg, intravenous immunoglobulin; mg, milligrams; MMF, mycophenolate mofetil; N/A, not available; rese-cel, resecabtagene autoleucel; TAC, tacrolimus; TIS, total improvement score.

1. Cabaletta Bio: Data on File. 2. Pinal-Fernandez I, et al. Ann Rheum Dis. 2024;83(11):1549–1560. 3. Galindo-Feria AS, et al. Best Pract Res Clin Rheumatol. 2022;36(2):101767. 4. Müller, F, et al. Nat Med. 2025;31(6):1793–1797.



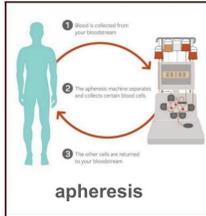
Rese-cel Manufacturing Strategy & Innovation

Cabaletta Bio[®]

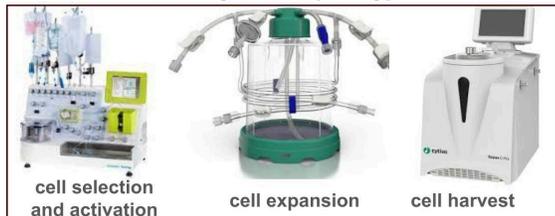
Rese-cel commercial process preliminary comparability established

Reliable process with >90% manufacturing success rate in first ~70 patients¹

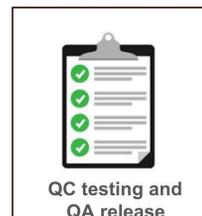
T cell collection



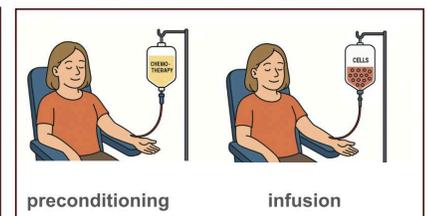
Rese-cel manufacture (9 day)



Product release



Rese-cel administration



- Process A - Early clinical process
- Process B – Commercial-ready manufacturing process
 - Substantially closed process reducing contamination risk
 - Partially automated manufacturing process improving process consistency
 - 3-fold higher capacity per facility footprint than original Process A
- FDA feedback received on comparability between Process A and Process B
 - Preliminary data enables use of previously dosed patients in safety database

1. Across Process A and Process B; only 1 failure attributed to patient starting material.

Advancing breakthrough innovations to improve scalability and costs

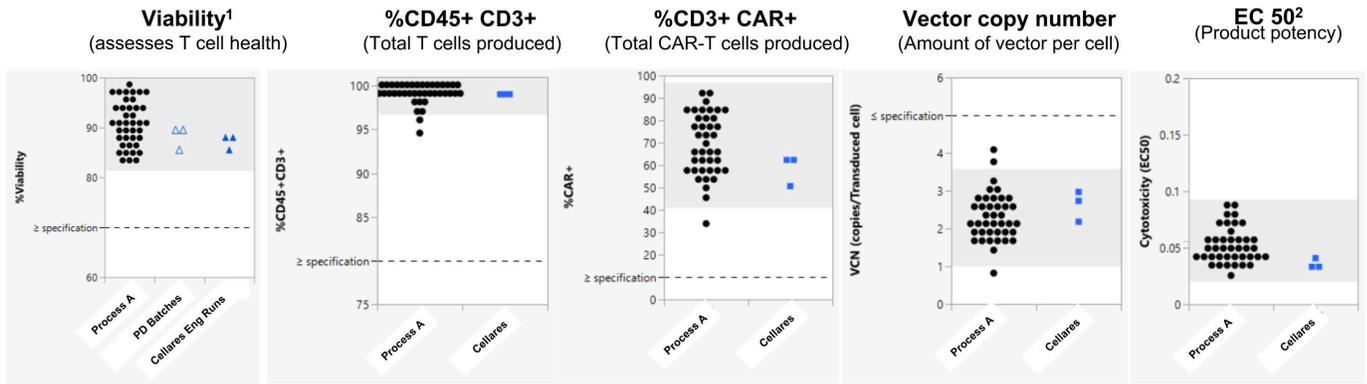
Automation and elimination of preconditioning and apheresis could enhance patient experience



1. Stratton et al, ESGCT 2024. Poster available at <https://www.cabalettatbio.com/technology/posters-publications>
 2. (https://d1io3yog0oux5.cloudfront.net/_cdcc45a1b07d9c1e0fc529e815f21ec3/cabalettatbio/db/947/8240/pdf/Whole+Blood+Mfg+Poster+ESGCT+2024.pdf)
 3. Automation run feasibility completed under TAP program. Video on Cellares technology can be viewed here: <https://vimeo.com/947203843/cd59569f16>.
 4. Under evaluation in an ongoing study in Pemphigus Vulgaris (NCT004422912); presented at ESGCT Conference 2025, presentation is available at <https://www.cabalettatbio.com/technology/posters-publications>.

Rese-cel engineering runs with Cellares supported INDa clearance

Three successful engineering runs³ completed in 2025 led to IND amendment (INDa) clearance



Clinical manufacturing experience with Cellares' automated manufacturing process anticipated in 1H26 to confirm GMP readiness, including supply chain readiness, with the Cellares manufacturing platform

Note: Shaded areas represent historical ranges defined by tolerance intervals that covers 90% of the population with 95% confidence.
 1. Cellares use Celleca for cell count to enable automated testing, while historical Process A data were collected using NC200. Data generated in Cabaletta Analytical Development lab using NC200 showed Engineering batches are within historical ranges.
 2. Effective Concentration 50, which is a measurement of product potency in a validated luciferase-based assay, designed for potency release testing on manufactured product. Lower EC50 indicates greater potency of product.
 3. Shaded area in the graphs indicate range of process comparability, based on historic process data.



Rese-cel – Initial Dose Data without Preconditioning

Cabaletta Bio[®]

Summary of rese-cel without preconditioning (PC), initial dose cohort*

Early clinical activity observed without preconditioning; low dose rese-cel may be a 'threshold' dose

- Clear evidence of biologic and clinical activity in all three PV patients in the initial dose cohort
 - PDAI improvements were present in all three and were compelling in two of the three patients
 - All patients remain off all immunomodulators while GCs are being tapered from low doses
- Peripheral B cell elimination was observed in the two patients with the greatest clinical response
 - BAFF induction in these two patients was at the low end of the range of rese-cel with PC
- Rese-cel persistence without PC was similar to patients who received rese-cel with PC
 - Peak persistence was not impacted by absence of PC and occurred slightly later without PC
- IFN γ induction in non-PC patients was at the higher end of the range observed in PC patients
 - Higher levels may be attributable to higher B cell burden in PV patients and/or absence of preconditioning
- Rese-cel was generally well tolerated in PV patients without PC¹
 - Based on limited data in the first three patients without PC, CRS rate was similar in rese-cel patients with PC

*As of 11 September 2025. Cabaletta Bio: Data on file.

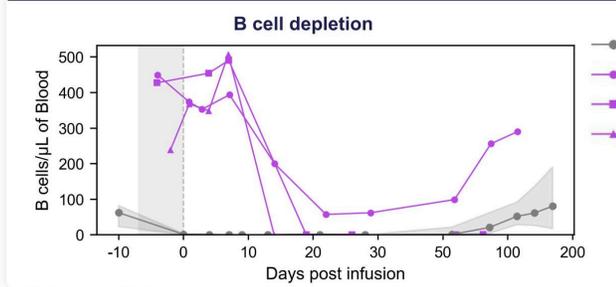
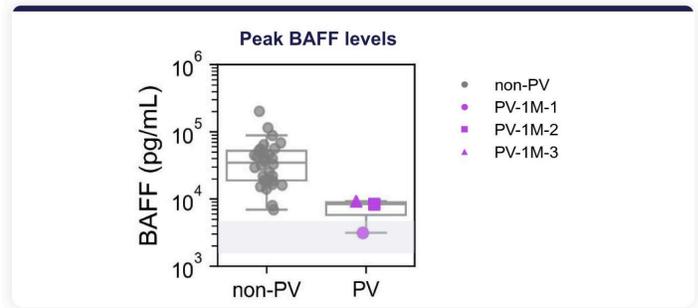
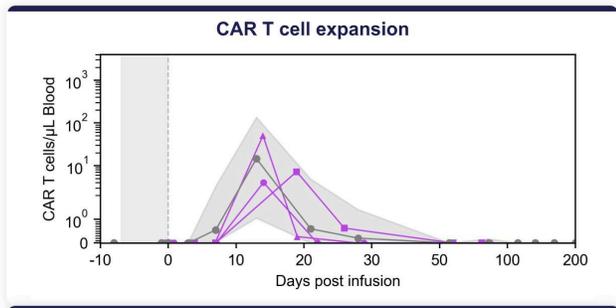
BAFF, B cell activating factor; CRS, cytokine release syndrome; GC, glucocorticoids; PDAI, pemphigus disease area index; PV, pemphigus vulgaris; rese-cel, resacabtagene autoleucel; IFN γ , interferon-gamma

1. Standard preconditioning in RESET trials consists of fludarabine 25 mg/m² x 3 days and cyclophosphamide 1000 mg/m² x 1 day.

Cabaletta Bio®

Similar PK & B cell depletion in rese-cel treated patients without PC*

Similar magnitude of rese-cel expansion & B cell depletion kinetics in patients treated with and without PC

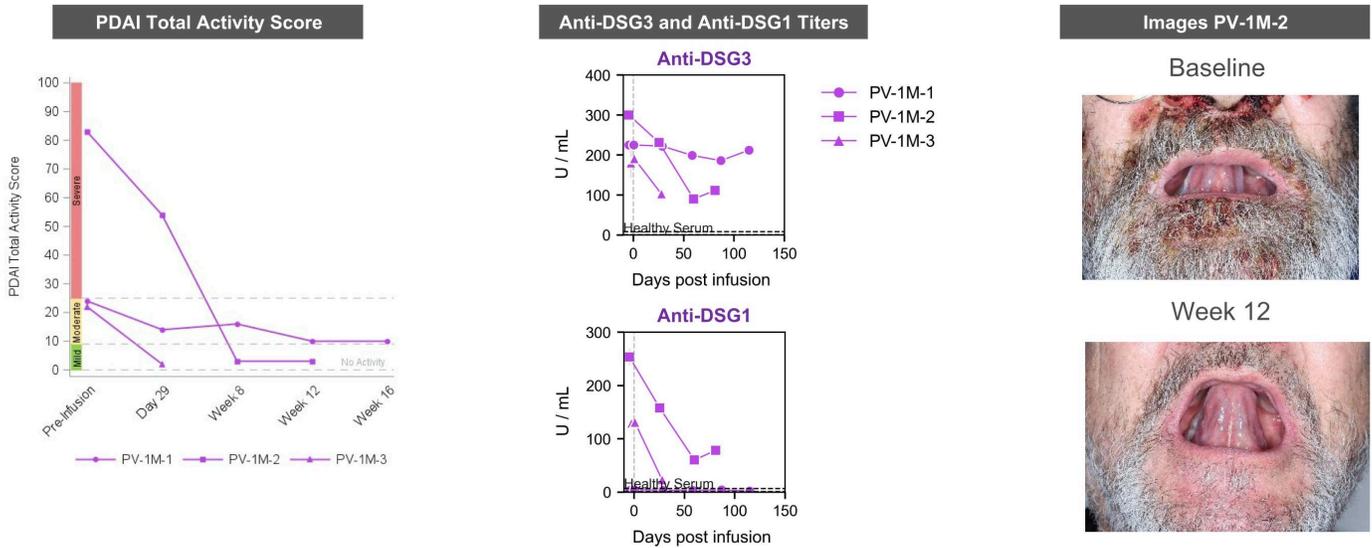


- PV-1M-2 & PV-1M-3 had 100% reduction of peripheral B cells at initial rese-cel dose
- BAFF levels in these two patients were at the low end of the range observed with rese-cel with PC

*As of 11 September 2025.
 Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1). Gray shading in BAFF plot is range of median serum BAFF induction observed in PV patients following rituximab (Nagele et. al, 2009 *Journal of Investigative Dermatology* and Hébert et. al, 2021 *Frontiers in Immunology*).
 Cabaletta Bio: Data on file.

Early clinical activity of rese-cel without preconditioning*

Near complete resolution of clinical symptoms and rapid reduction in autoantibodies in 2 of 3 patients



PDAI improvements were most significant in the two patients who experienced peripheral B cell elimination; all three patients were off immunomodulators as of the data cut-off

*As of 11 September 2025. Cabaletta Bio: Data on file. Disease severity intervals as defined Krain RL, et al. Br J Dermatol. 2021;184(5): 975-977. Gray vertical dotted line indicates day of rese-cel infusion (study visit Day 1).



Lupus: Unmet Need & Clinical Data

Cabaletta Bio[®]

SLE & LN: Represent a high unmet clinical need

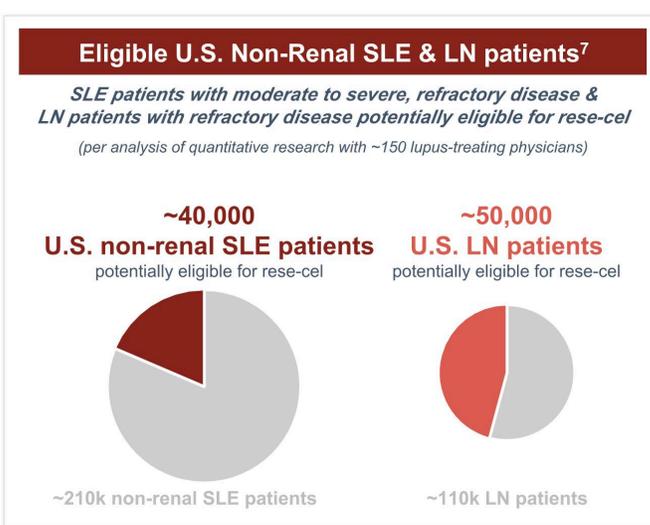
Increased mortality risk & negative impact on quality of life for patients with SLE & LN

> SLE is a chronic autoimmune condition that can affect nearly every organ system¹

- Most common in women, with disease onset generally between ages of 20-40 years
- Common symptoms include severe fatigue, joint pain and swelling, skin rashes, ulcers & Raynaud's phenomenon
- >50% of patients develop permanent widespread organ damage, caused by disease & current treatments²
- Standardized mortality ratio from 2.4-4.5 for SLE patients^{3,4}

> ~30-40% of SLE patients develop LN, with inflammation & damage within the kidneys

- LN may present silently or with symptoms such as proteinuria, hematuria, swelling & elevated blood pressure
- 10-30% of patients with LN will progress to ESRD, requiring dialysis or transplantation within the first decade of their disease^{5,6}



Market research indicates opportunity to achieve superior penetration and potentially further expand the market through introducing a no preconditioning CAR T alternative for patients

ESRD, end-stage renal disease; LN, lupus nephritis; SLE, systemic lupus erythematosus.
1. Zen M, et al. Eur J Intern Med. 2023;112:45-51. 2. Rahman P, et al. Lupus. 2001;10(2):93-96. 3. Singh, R, et al. Lupus 27.10 (2018): 1577-1581. 4. Murimi-Worstell, I, et al. BMJ 10.5 (2020): e031850. 5. Lichtnekert, J. Nature reviews rheumatology 20.11 (2024): 699-711. 6. Tektonidou, M. Arthritis & rheumatology 68.6 (2016): 1432-1441. 7. Results from quantitative survey of U.S. lupus-treating physicians (rheumatologists & nephrologists), conducted 2Q25. N = ~150.

Baseline characteristics: First 9 patients in RESET-SLE*

All patients had active, refractory disease and had failed multiple B cell-targeted therapies

Cohort	Non-renal SLE (n=5)	LN (n=4)
Age, years, mean (min, max)	~34 (26, 44)	~26 (18, 35)
Female, n (%)	4 (80)	3 (75)
Time from diagnosis to screening, years, mean (min, max)	11.5 (6.1, 17.3)	7.3 (2.2, 15.7)
Autoantibodies (%)	dsDNA: 100% Sm: 60%	dsDNA: 75% Sm: 75%
Baseline disease activity†	SLEDAI-2K (median)	
	10	16
	UPCR (mg/mg) (median)	
	1.09§	3.45
Therapies at screening:		
Systemic GCs	80%	50%
≤2 SLE immunomodulators‡	60%	50%
≥3 SLE immunomodulators‡	40%	50%
GC dose at screening, mg/day, mean (min, max)	13.4 (0, 30)	6.25 (0, 20)

*As of 11 Sep, 2025.

†Baseline disease activity = activity before preconditioning.

‡SLE medications may include biologics, anti-malarials, and immunosuppressants.

§N=2 patients included in UPCR analysis: SLE-1 had pure Class V LN and extra-renal SLE disease activity and SLE-5 had Class II LN with moderate to severe chronicity and extra-renal disease activity that met inclusion criteria for the non-renal cohort.

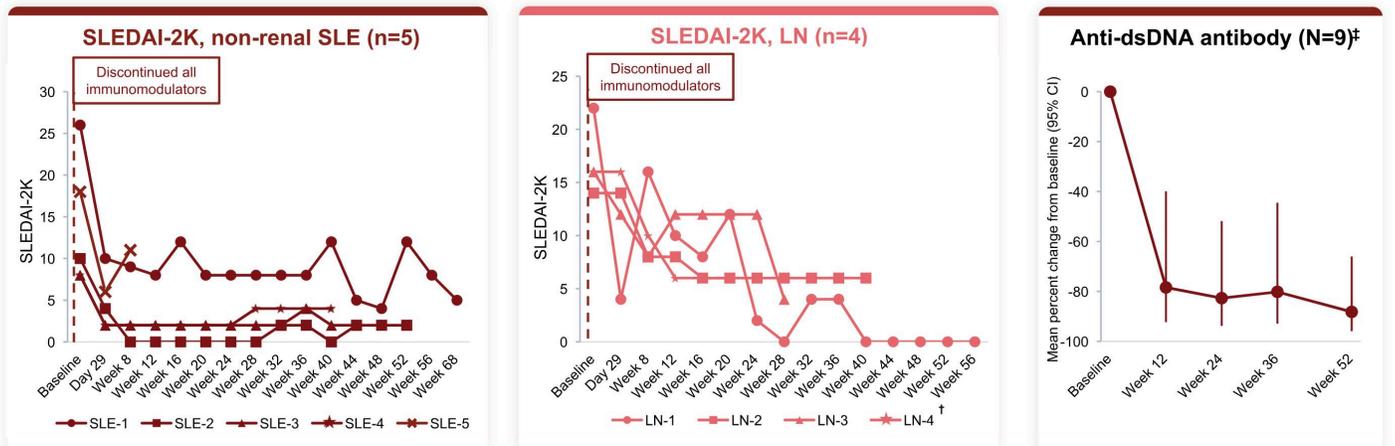
dsDNA, double-stranded DNA; GC, glucocorticoid; LN, lupus nephritis; RESET, REStoring SEIf-Tolerance; SLE, systemic lupus erythematosus; SLEDAI-2K, SLE Disease Activity Index 2000; Sm, Smith;

UPCR, urine protein-to-creatinine ratio.

Cabaletta Bio: Data on File.

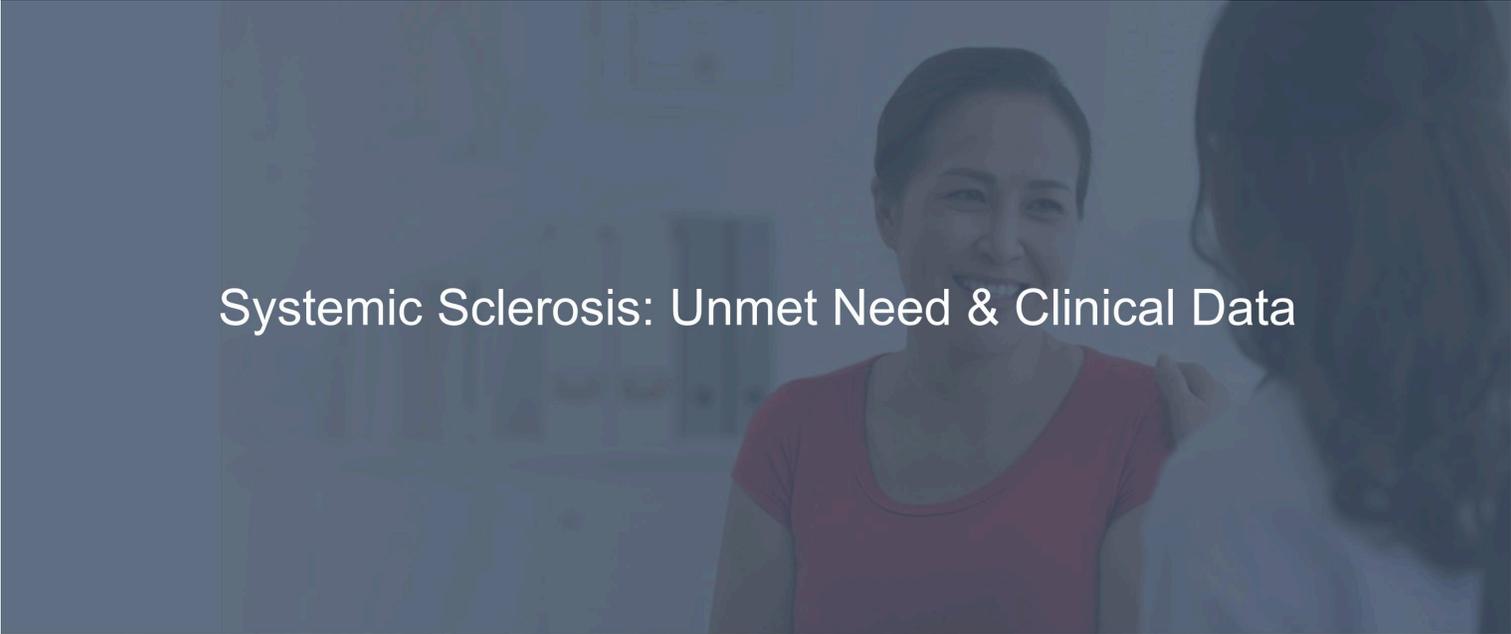
Efficacy data following rese-cel infusion*

Improvements in SLEDAI-2K over time and significant reduction in anti-dsDNA antibodies after discontinuing immunomodulators



Clinical & translational data in lupus for rese-cel with preconditioning (PC) along with initial no PC data in PV support expansion of simplified no PC regimen into lupus; initial clinical data anticipated in 1H26

*As of 11 Sep, 2025.
 †Week 20 urinalysis components of the SLEDAI-2K (WBC, RBC and casts) imputed from Week 16 for total SLEDAI-2K score.
 ‡Assessed by ELISA at a central lab at baseline, weeks 12, 24, 36 and 52.
 dsDNA, double-stranded DNA; LN, lupus nephritis; rese-cel, resacetabtagene autoleucel; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000.
 Cabaletta Bio: Data on File.



Systemic Sclerosis: Unmet Need & Clinical Data

Cabaletta Bio[®]

Systemic sclerosis: Profound unmet need & limited options

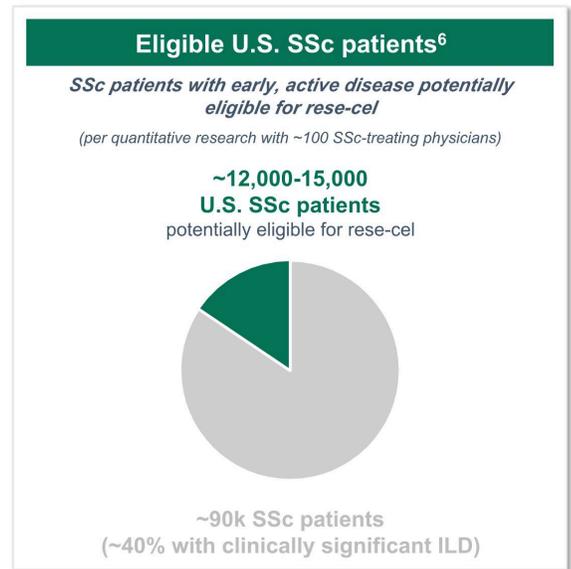
Associated with progressive morbidity and high mortality^{1,2}

➤ Rare, potentially life-threatening autoimmune disease¹

- Characterized by progressive skin & internal organ fibrosis¹
- Deep, tissue-level B cell-driven autoimmunity, with activated B cells & autoantibodies, promotes inflammation & organ damage³

➤ Patients experience a progressive & often fatal course

- Typically, middle age onset and more common in females⁴
- Highest mortality of all rheumatological diseases & significant burden from persistent skin & organ manifestations^{4,5}
 - Mean survival is ~12 years from diagnosis
- Need for disease-modifying therapies across all SSc subsets⁵
 - FDA-approved agents for SSc-ILD slow but do not stabilize or improve lung progression
 - Approved based on 1-year primary endpoints
 - No existing treatments capable of halting SSc pathology other than AHSCT, which carries high risk



AHSCT, autologous hematopoietic stem cell transplantation; ILD, interstitial lung disease; SSc, systemic sclerosis.

1. Allanore Y, et al. Nat Rev Dis Primers. 2015;1:15002. 2. Denton CP, et al. Lancet. 2017;390(10103):1685-1699. 3. Thoreau B, et al. Front Immunol. 2022;13:933468. 4. Truchetet ME, et al. Clin Rev Allergy Immunol. 2023;64(3):262-283. 5. Pope JE, et al. Nat Rev Rheumatol. 2023;19(4):212-226. 6. Results from quantitative survey of U.S. SSc-treating physicians (rheumatologists), conducted 3Q25. N = ~100.

Baseline characteristics: First 6 Patients in RESET-SSc*

All patients had active, refractory disease and were on 1 to 3 disease-specific therapies at screening

Patient / Cohort	Severe Skin Cohort			Organ Cohort		
	SSc-Skin-1	SSc-Skin-2	SSc-Skin-3	SSc-Organ-1	SSc-Organ-2	SSc-Organ-3
Age, sex	66 F	55 F	59 M	70 M	43 F	60 F
Disease duration (y)	~2	~0.5	~2	~5	~2	~1
Autoantibodies	RNA Pol III	ScI-70	RNA Pol III	□	ScI-70	ScI-70
Baseline† mRSS	42	38	45	12	9	24
Baseline† HAQ-DI	2.25	2.125	2.875	0.75	0.50	2.50
Baseline† PFTs (% predicted)	FVC: 91 DLCO: 70	FVC: 93 DLCO: 58	FVC: 50 DLCO: 89	FVC: 69 DLCO: 58	FVC: 76 DLCO: 66	FVC: 83 DLCO: 78
ILD presence‡	✓	□	□	✓	✓	✓
Therapies at Screening	MMF	GC, MPA	MMF	MMF, TOC, NIN	GC, TOC	MMF, IVIg, HCQ

*As of 11 Sep, 2025; primary endpoint is incidence and severity of adverse events through Day 29

†Baseline disease activity = activity before preconditioning.

‡Per patient history and HRCT.

DLCO, % predicted diffusing capacity for carbon monoxide; FVC, forced vital capacity; GC, glucocorticoid; HAQ-DI, Health Assessment Questionnaire Disability Index; HCQ, hydroxychloroquine; HRCT, high-resolution computed tomography; ILD, interstitial lung disease; IVIg, intravenous immune globulin; MMF, mycophenolate mofetil; MPA, mycophenolic acid; mRSS, modified Rodnan skin score; NIN, nintedanib; SAE, serious adverse event; PFT, pulmonary function test; RESET, REStoring SEIf-Tolerance; RNA Pol III, ribonucleic acid polymerase III; ScI-70, anti-topoisomerase I antibody; SSc, systemic sclerosis; TOC, tocilizumab; y, years.

Cabaletta Bio: Data on File.

SSc: Efficacy data following rese-cel infusion*

As of the data cut-off, 4 of 4 SSc patients with ≥12 weeks follow-up had FVC stabilization or improvement

Patient / Cohort	Severe Skin Cohort			Organ Cohort		
	SSc-Skin-1	SSc-Skin-2	SSc-Skin-3	SSc-Organ-1	SSc-Organ-2	SSc-Organ-3
Latest follow-up	Week 48	Week 24	Day 29	Week 16	Week 12	Day 29
GC-free	✓	✓	✓	✓	✓	– ^{††}
IM-free	✓	✓	✓	✓	✓	✓
Antibody and trend [†]	RNA Pol III ↓	Scl-70 ↓ ^{**}	RNA Pol III; <i>too early</i>	None detected	Scl-70 ↓	Scl-70; <i>too early</i>
Revised CRISS-25 [‡] (time to response)	✓ Week 12	✓ Week 24	N/A	✓ Week 12	✓ Week 12	N/A
Revised CRISS-50 [‡] (time to response)	✓ Week 12 [§]	✓ Week 24	N/A	–	✓ Week 12	N/A
mRSS (baseline to latest follow-up)	42→23	38→27	45→32	12→6	9→4	24→22
FVC [¶] [%] (baseline to latest follow-up)	91→105	93→100	N/A	69→72	76→77	N/A
DLCO [¶] [%] (baseline to latest follow-up)	70→81	58→75	N/A	58→58	66→75	N/A

SSc patients were able to achieve meaningful clinical responses off all immunomodulators and off or tapering steroids

*As of 11 Sep, 2025; primary endpoint is incidence and severity of adverse events through Day 29.

[†]Reflects trend from baseline to latest available timepoint.

[‡]Revised CRISS is evaluated at Weeks 12, 24, 36, and 52. PFTs from Week 24 are carried forward for Week 36 evaluation.

[§]Revised CRISS-50 met at Weeks 12 and 36. Not met at Week 24.

[¶]DLCO and FVC are evaluated at Weeks 12 and 24.

^{**}Based on the research-based, qualified, quantitative Luminex assay.

^{††}Tapering GC.

CRISS, Composite Response Index in Systemic Sclerosis; DLCO, % predicted diffusing capacity for carbon monoxide; FVC, forced vital capacity; GC, glucocorticoid; IM, immunomodulatory medication; mRSS, modified Rodnan Skin Score (measure of skin thickness in SSc across 17 body areas, with a maximum score of 51); N/A, not applicable; rese-cel, resecabtagene autoleucel; RNA Pol III/RP11, ribonucleic acid polymerase III; Scl-70, anti-topoisomerase I antibody; SSc, systemic sclerosis.

Cabaletta Bio: Data on File.

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Myasthenia Gravis: Unmet Need & Clinical Data

Cabaletta Bio[®]

Myasthenia gravis: Significant disease & treatment burden

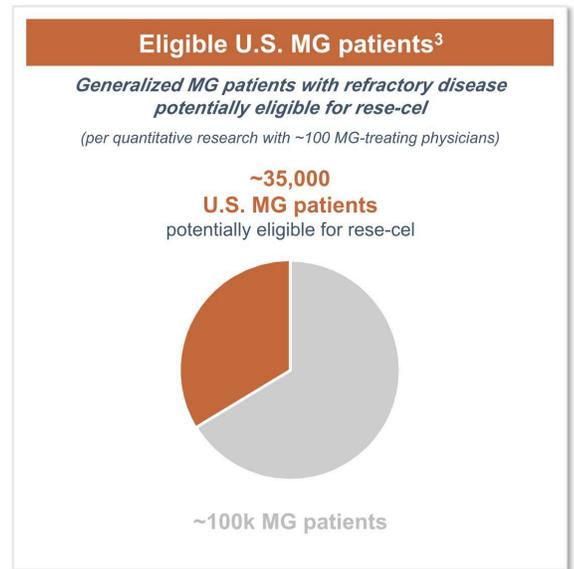
High impact of disease due to patient symptoms & cost burden, particularly for refractory patients

> Serious, chronic autoimmune neuromuscular disorder¹

- Characterized by defective transmission at the neuromuscular junction, resulting in weakness of the skeletal muscles
- Typically associated with autoantibodies (e.g. AChR, MuSK, LRP4)
- Symptoms range from ocular involvement, including double vision and ptosis, to severe weakness of the limb, bulbar, trunk, and respiratory muscles, which is worsened with exertion
- Mortality rate estimated to be 5-9%, primarily driven by myasthenic crises, or respiratory crises requiring ventilation²

> Treatments have transient effect & involve long-term broad immunosuppression¹

- Available therapeutic options focus on specific symptoms and can be associated with serious long-term side effects
- Mainstays include steroids, immunosuppressants (e.g., mycophenolate), FcRn antagonists, complement inhibitors and rituximab
- MG represents a significant healthcare cost burden in the US, particularly for patients whose disease is inadequately controlled



1. Gilhus NE, et al. *Eur J Neurol.* 2024. 2. Dresser L, et al. *J Clin Med.* May 2021. 3. Results from quantitative survey of U.S. MG-treating physicians (neurologists), conducted 3Q25. N = ~100.

Baseline characteristics: First 4 patients in RESET-MG*

Patient / Cohort (latest follow-up)	AChR Positive		AChR Negative	
	AChR-pos-1 (Week 8)	AChR-pos-2 (Week 4)	AChR-neg-1 (Week 20)	AChR-neg-2 (Week 8)
Age, sex	62, M	44, F	54, F	70, F
Disease duration (approx. years)	1	6	4	1
Autoantibodies	AChR	AChR	Seronegative [‡]	Seronegative [‡]
QMG [†]	11	18	22	21
MG-ADL [†]	15	13	17	14
Therapies at screening	GC, AZA, IVIg, PYR	EFG, PYR	GC, PYR, PLA	PYR, MMF, ROZ
Other prior therapies	–	GC, IVIg, MMF, AZA, ECU, PLA	IVIg, AZA, RTX, ECU, EFG	IVIg
GC dose at screening (mg/day)	25	–	15	–

*As of 11 Sep, 2025.

[†]Baseline disease activity = activity before preconditioning.

[‡]Seronegative = no anti-AChR, anti-MuSK and anti-LRP4 antibodies

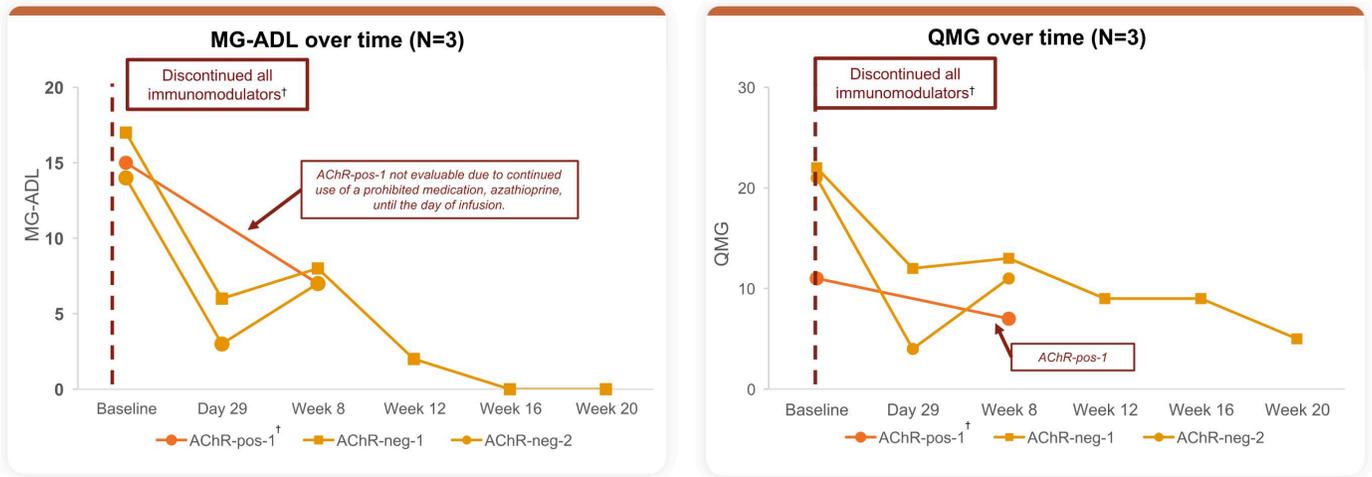
AChR, acetylcholine receptor; AZA, azathioprine; ECU, eculizumab; EFG, efgartigimod; GC, glucocorticoid; IVIg, intravenous immunoglobulin; MG, myasthenia gravis; MG-ADL, MG – Activities of Daily Living;

MMF, mycophenolate mofetil; PLA, plasmapheresis; PYR, pyridostigmine; ROZ, rozanolixizumab; RTX, rituximab; QMG, Quantitative Myasthenia Gravis Score; RESET, REstoring SElf-Tolerance.

Cabaletta Bio: Data on File.

MG: Efficacy data following rese-cel infusion*

As of latest follow-up, both evaluable patients showed improvement off immunomodulators and steroids



**RESET-MG is now fully enrolled in both cohorts
Cabaletta plans to announce registrational cohort design in mid-26**

*As of 11 Sep. 2025.

†AChR-pos-1, Day 29 visit data unavailable. In AChR-pos-1, azathioprine, a prohibited medication, was continued until the day of infusion (Day 1). IVIg was stopped prior to rese-cel infusion and restarted 4 weeks after infusion for continued MG symptoms.

AChR, acetylcholine receptor; AZA, azathioprine; IVIg, intravenous immunoglobulin; MG, myasthenia gravis; MG-ADL, MG – Activities of Daily Living; QMG, Quantitative Myasthenia Gravis Score; rese-cel, resecabtagene autoleucel.
Cabaletta Bio: Data on file.



Corporate Summary

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Cabaletta Bio leadership

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

LEADERSHIP TEAM

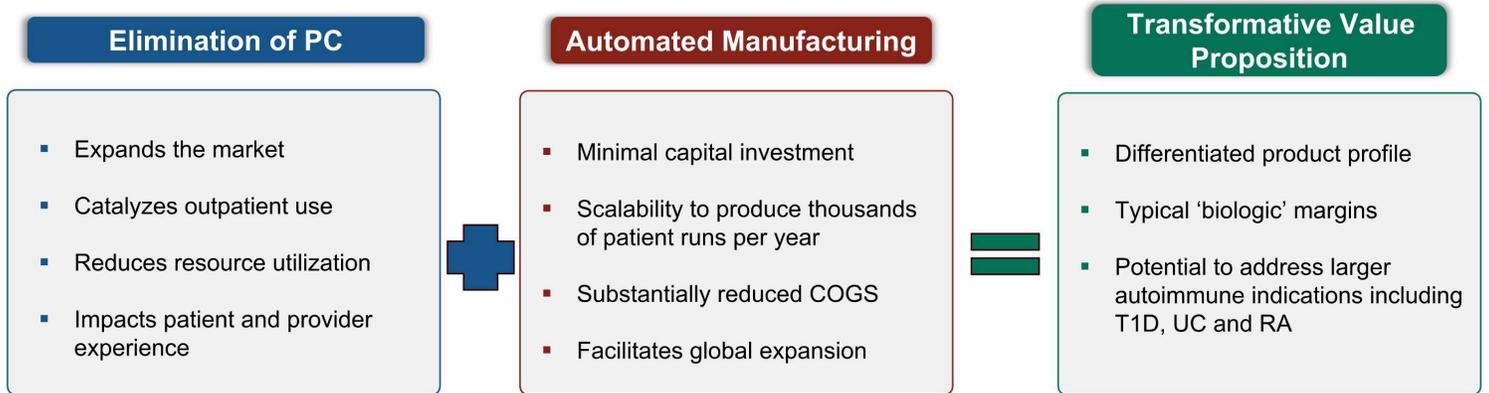
 <p>Steven Nichtberger, M.D. President, CEO & Chairman</p> 	 <p>Samik Basu, M.D. Chief Scientific Officer</p> 	 <p>Gwendolyn Binder, Ph.D. President, Science & Technology</p> 	 <p>David J. Chang, M.D., M.P.H., FACR Chief Medical Officer</p> 	 <p>Arun Das, M.D. Chief Business Officer</p> 	 <p>Steve Gavel Chief Commercial Officer</p> 
 <p>Michael Gerard General Counsel</p> 	 <p>Heather Harte-Hall Chief Compliance Officer</p> 	 <p>Anup Marda Chief Financial Officer</p> 	 <p>Nicolette Sherman Chief HR Officer</p> 	 <p>Sarah Yuan Chief Technology Officer</p> 	

SCIENTIFIC ADVISORY BOARD

- | | |
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| <p>Aimee Payne, M.D., Ph.D.
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Co-Founder and Co-Chair</p> <p>Georg Schett, M.D.</p> <p>Jay Siegel, M.D.</p> |
|---|--|

Transformative value proposition with PC elimination & automation

Removing PC should expand access while automated manufacturing should reduce COGS & increase scale



1H26

*Initial clinical data without PC from the first SLE cohort
and initial clinical experience with rese-cel manufactured by Cellares*

2H26

*Durability data without PC from the SLE & PV dose cohorts
and longer-term data from patients receiving rese-cel manufactured by Cellares*

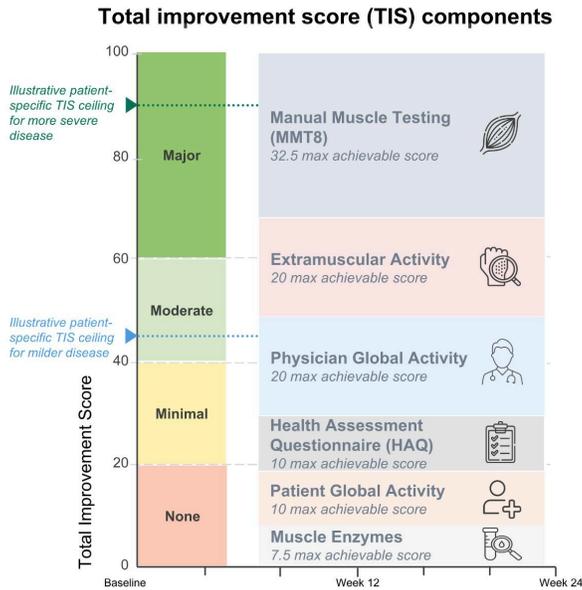


Appendix

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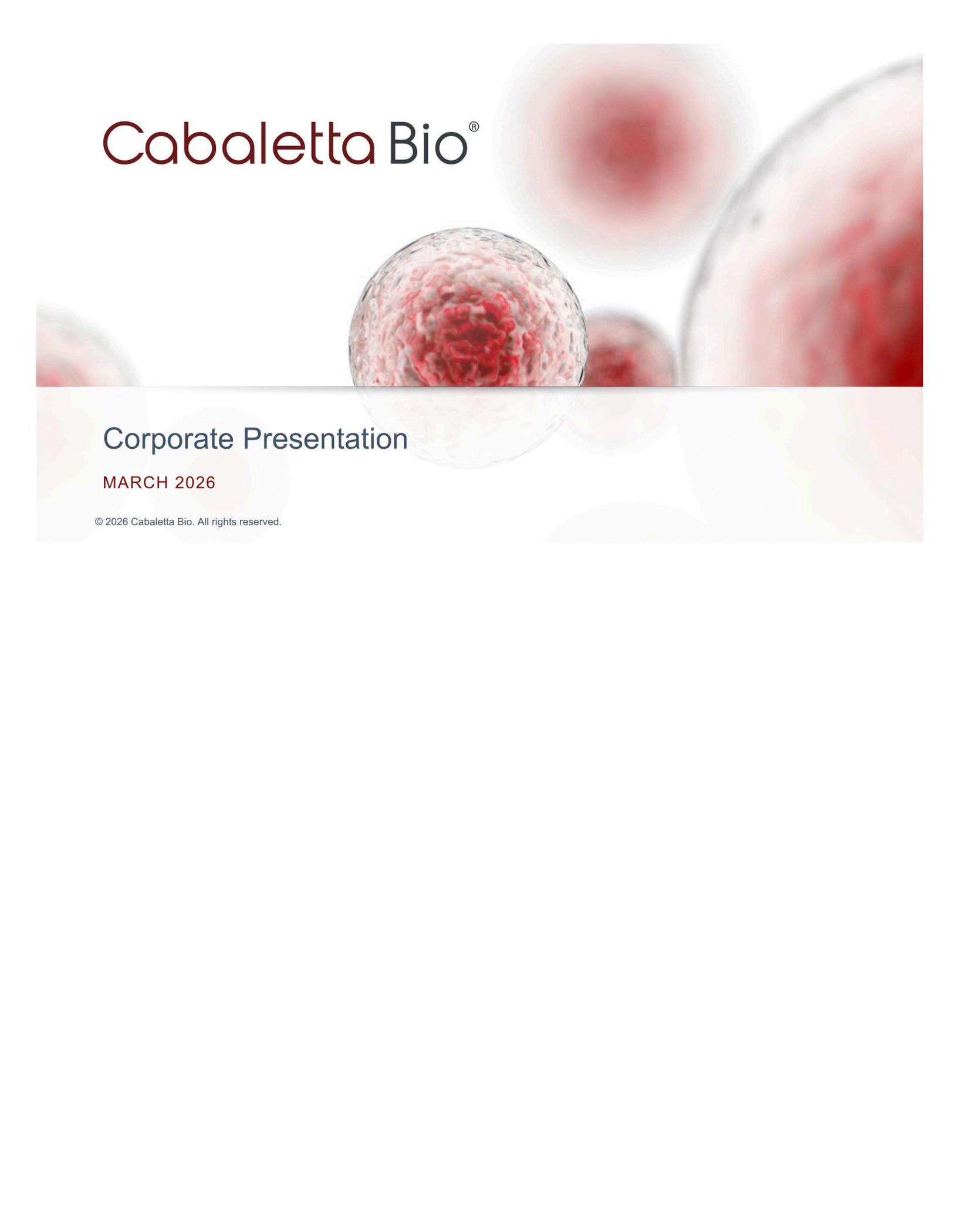
Myositis outcomes captured through validated composite endpoint

TIS is a composite tool measuring a patient's relative improvement from their baseline



- TIS developed via conjoint analysis based continuous model using **absolute percentage change** in 6 core set measures (CSM): MMT8, Extramuscular Activity, Physician Global Activity, Health Assessment Questionnaire, Patient Global Activity, and Muscle Enzymes
- TIS is the sum of improvement scores in the 6 CSMs, with **ceiling of potential effect likely higher in DM and ASyS than in IMNM given minimal extramuscular involvement**

1. ASyS – antisynthetase syndrome; CSM – core set measure; DM – dermatomyositis; IMNM – immune-mediated necrotizing myopathy; IVIg – intravenous immunoglobulin.
 2. Aggarwal R et al. NEJM. 2022;387(14):1264-1278.

The background of the slide features a microscopic view of several spherical cells. The most prominent cell in the center is in sharp focus, showing a highly textured, porous surface with a vibrant red color. Other cells are visible in the foreground and background, but they are out of focus, appearing as soft, blurred red and white spheres. The overall aesthetic is clean and scientific.

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Corporate Presentation

MARCH 2026

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