

November 10, 2025

Cabaletta Bio®

Cabaletta Bio Reports Third Quarter 2025 Financial Results and Provides Business Update

Rese-cel data presented at multiple medical meetings demonstrated potentially transformative, drug-free clinical responses with a favorable safety profile for autoimmune patients supporting outpatient use

All myositis patients in the Phase 1/2 DM/ASyS cohort with sufficient follow-up who would have met key criteria for the registrational cohort met the registrational, 16-week primary endpoint

Planned BLA submission for rese-cel in 2027 based on 14-patient, single-arm DM/ASyS registrational cohort initiating enrollment this quarter within the RESET-Myositis™ trial

FDA alignment on additional registrational cohort designs for RESET-SSc™ and RESET-SLE™ anticipated by year-end 2025

PHILADELPHIA, Nov. 10, 2025 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for patients with autoimmune diseases, today reported financial results for the third quarter ended September 30, 2025, and provided a business update.

“Our team continued to execute with discipline and precision to extend our leadership through the RESET™ clinical development program. Rapid enrollment has resulted in multiple clinical data presentations highlighting rese-cel’s ability to deliver drug-free, transformative clinical responses for patients across multiple autoimmune diseases,” said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “In addition, the early no preconditioning data from our initial dose cohort support our plan to evaluate the efficacy and durability of rese-cel in lupus and other autoimmune patients using a single, weight-based dose without preconditioning.”

Recent Operational Highlights and Upcoming Anticipated Milestones

Rese-cel: Rese-cel (rescabtagene autoleucel, formerly CABA-201) 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 is intended to transiently 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 diverse and growing range of autoimmune diseases in rheumatology, neurology and dermatology.

Clinical Development

- **Presented positive new and longer-term clinical data from 32 patients across four autoimmune trials:** At multiple medical meetings in October 2025, Cabaletta shared encouraging results from patients treated with rese-cel in myositis, systemic sclerosis, lupus, and myasthenia gravis, including full Phase 1/2 data from RESET-Myositis and preliminary data from RESET-SSc, RESET-SLE, and RESET-MG™ trials. These findings highlight rese-cel's potential to deliver transformative, drug-free responses for patients with a favorable safety profile that can support outpatient use.
- **Initial, low-dose no preconditioning data presented and expansion of approach into lupus:** At the 2025 European Society of Gene & Cell Therapy Annual Congress, Cabaletta presented initial data from the RESET-PV™ trial evaluating a low dose of rese-cel without preconditioning in patients with pemphigus vulgaris, demonstrating complete B cell depletion in 2 of 3 patients along with early clinical responses with a generally well-tolerated profile. Based on these data, Cabaletta is expanding patient enrollment in the RESET-PV trial at the current dose, with the potential to evaluate higher doses, as warranted. In addition, Cabaletta is incorporating a new dose-escalation cohort in the RESET-SLE trial to evaluate rese-cel without preconditioning given the clinical responses observed in lupus following complete B cell depletion after administration of rese-cel with preconditioning.
- **Initiation of myositis registrational DM/ASyS cohort anticipated by year-end 2025:** Consistent with the previously announced alignment with the U.S. Food and Drug Administration (FDA) on registrational cohort design, which is based on several interactions, including direct review and feedback on the registrational trial protocol in August 2025, we are aligned on the dermatomyositis (DM) and antisynthetase syndrome (ASyS) registrational cohort with a 16-week primary endpoint of moderate or major total improvement score response while off immunomodulators and on no or low-dose steroids. The planned size of 14 patients for the registrational cohort is based on the assumed treatment effect of rese-cel in DM/ASyS patients and an estimated background rate. The estimated background rate will be determined from an external myositis patient registry, as aligned with the FDA, and will include patients with similar inclusion criteria as those in the registrational DM/ASyS cohort. In the Phase 1/2 DM/ASyS cohort, all patients with sufficient follow-up who would have met key criteria for the registrational cohort met the registrational primary endpoint. If successful, data from the DM/ASyS cohort will be used in part to support the Company's first projected Biologics License Application (BLA) submission for rese-cel in myositis in 2027.
- **Additional clinical data from RESET trials expected throughout 2026:** On December 6, 2025, Cabaletta will present a poster titled "Mechanistic basis of the acute safety profile of rese-cel, an autologous CD19-CAR T, in patients with autoimmune disease treated in four ongoing phase 1/2 clinical trials" at the 67th American Society of Hematology Annual Meeting and Exposition, taking place in Orlando, FL. In addition, Cabaletta plans to present complete Phase 1/2 data from the RESET-SSc and RESET-SLE trials in the first half of 2026 and from the RESET-MG trial in the second half of 2026. The Company also anticipates clinical data on rese-cel without preconditioning from the initial RESET-SLE dose-escalation cohort and additional dosing from the RESET-PV trial in 2026.

Regulatory

- **New PRIME, RMAT and Fast Track regulatory designations granted by EMA and FDA:** The Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) granted PRIME scheme access for rese-cel for the treatment of myositis during its September 2025 meeting. Through PRIME, the EMA offers early and proactive support to medicine developers to optimize the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications. In addition, the FDA has granted new regulatory designations to rese-cel, including Regenerative Medicine Advanced Therapy (RMAT) designation for the treatment of systemic lupus erythematosus and lupus nephritis and Fast Track Designation for generalized myasthenia gravis.
- **FDA alignment on additional registrational cohort designs expected through 2026:** Cabaletta expects to align with the FDA on key registrational design elements for the RESET-SSc and RESET-SLE trials by year-end 2025 and for the RESET-MG trial in the first half of 2026. Subject to clinical data and regulatory alignment on registrational cohort design elements for these trials, the Company expects to initiate enrollment in registrational cohorts in 2026.

Corporate Updates

- **Appointment of Chief Commercial Officer:** In October 2025, Steve Gavel was appointed Chief Commercial Officer. Mr. Gavel brings highly relevant CAR T experience from Legend Biotech where he led the launch and commercialization of CARVYKTI® from 2018 until 2025. In his role at Cabaletta, he will lead all aspects of global commercial strategy and execution for rese-cel as well as potential future pipeline opportunities.

Third Quarter 2025 Financial Results

- Research and development expenses were \$39.8 million for the three months ended September 30, 2025, compared to \$26.3 million for the same period in 2024.
- General and administrative expenses were \$6.8 million for the three months ended September 30, 2025, compared to \$6.8 million for the same period in 2024.
- As of September 30, 2025, Cabaletta had cash, cash equivalents and short-term investments of \$159.9 million, compared to \$164.0 million as of December 31, 2024. The Company expects that its cash position as of September 30, 2025, will enable it to fund its operating plan into the second half of 2026.

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies designed specifically for

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

Forward-Looking Statements

This press release contains “forward-looking statements” of Cabaletta Bio within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including without limitation, express or implied statements regarding: Cabaletta's business plans and objectives as a whole; Cabaletta's ability to realize its vision of launching the first curative targeted cell therapy designed specifically for patients with autoimmune diseases; Cabaletta's ability to successfully complete research and further development and commercialization of its drug candidates in current or future indications, including the timing and results of Cabaletta's clinical trials and its ability to conduct and complete clinical trials; expectation that clinical results will support rese-cel's safety and activity profile; statements regarding the timing of interactions with regulatory authorities, including such authorities' review of safety information from Cabaletta's ongoing clinical trials and alignment with regulatory authorities on potential registrational pathway for rese-cel; Cabaletta's ability to leverage its emerging clinical data and its efficient development strategy; Cabaletta's belief that its new data demonstrates rese-cel's ability to deliver drug-free, transformative clinical responses for patients across multiple autoimmune diseases and that the early no preconditioning data from its initial dose cohort has opened new opportunities to potentially treat autoimmune patients using a single weight-based dose of rese-cel without preconditioning; Cabaletta's expectations that the milestones it has achieved underscores the potential of rese-cel to redefine treatment paradigms and bring drug-free remission to patients with high unmet need and also that its findings highlight rese-cel's potential to deliver transformative, drug-free responses for patients with a favorable safety profile that can support outpatient use; 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, including its belief that rese-cel has the potential to reset the immune system and achieve durable clinical responses without the need for chronic therapy; 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 data read-outs or otherwise; Cabaletta's ability to initiate the myositis registrational trial and timing thereof; Cabaletta's plans to expand patient enrollment in the RESET-PV trial at the current dose, with the potential to evaluate higher doses; Cabaletta's expectations regarding the new dose-escalation cohort in the RESET-SLE trial to evaluate rese-cel without preconditioning based on the clinical responses observed in lupus; Cabaletta's plans to initiate enrollment in the registrational DM/ASyS cohort in 2025; Cabaletta's plans to announce additional clinical data from RESET trials throughout 2026; Cabaletta's expectations around alignment with FDA on key registrational design elements

for the RESET-SSc and RESET-SLE trials by year-end 2025 and for the RESET-MG trial in the first half of 2026; Cabaletta's expectations to initiate enrollment in registrational cohorts in 2026; 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 and Cabaletta's use of capital, expense and other financial results in the future and its ability to fund operations into the second half of 2026.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks related to regulatory filings and potential clearance; the risk that signs of biologic activity or persistence may not inform long-term results; Cabaletta's ability to demonstrate sufficient evidence of safety, efficacy and tolerability in its preclinical studies and clinical trials of rese-cel; the risk that the results observed with the similarly-designed construct employed in academic publications, including due to the dosing regimen, are not indicative of the results we seek to achieve with rese-cel; risks that 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

Three Months Ended September 30,		Nine Months Ended September 30,	
2025	2024	2025	2024

	unaudited		unaudited	
Operating expenses:				
Research and development	\$ 39,824	\$ 26,290	\$ 106,480	\$ 71,671
General and administrative	6,764	6,756	23,150	19,685
Total operating expenses	46,588	33,046	129,630	91,356
Loss from operations	(46,588)	(33,046)	(129,630)	(91,356)
Other income:				
Interest income	1,808	2,417	4,705	8,078
Interest expense	(584)	–	(1,449)	–
Other income, net	498	–	437	–
Net loss	(44,866)	(30,629)	(125,937)	(83,278)
Net loss per share of voting and non-voting common stock, basic and diluted	\$ (0.44)	\$ (0.62)	\$ (1.75)	\$ (1.69)

Selected Balance Sheet Data

	September 30, 2025	December 31, 2024
	(unaudited)	
Cash, cash equivalents and investments	\$ 159,931	\$ 163,962
Total assets	189,759	185,046
Total liabilities	50,293	32,711
Total stockholders' equity	139,466	152,335

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

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Source: Cabaletta Bio