March 23, 2026

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 (GLOBE NEWSWIRE) -- 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 (resecabtagene 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. 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

	Three months ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
	Unaudited			
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	(41,919)	(32,586)	(167,856)	(115,864)
Net loss per voting and non-voting share, basic and diluted	$ (0.40)	$ (0.65)	$ (2.10)	$ (2.34)

Selected Balance Sheet Data

	December 31,	
	2025	2024
	Unaudited	
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

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Cabaletta Bio®

Source: Cabaletta Bio