May 14, 2026

Cabaletta Bio Reports First Quarter 2026 Financial Results and Provides Business Update

Preconditioning-free (PC-free) 6-to-9-month clinical data with a single infusion of the lowest dose of rese-cel in the RESET-PV® study presented today at ASGCT 2026 Annual Meeting along with initial rese-cel translational data using Cellares' industrialized, automated manufacturing

PC-free rese-cel initial data from the lowest dose RESET-SLE™ cohort expected in 1H26

Pivotal RESET-Myositis® cohort with outpatient dosing option progressing to support first planned BLA submission for rese-cel next year

Second pivotal indication for advancement to be announced after presentation of complete Phase 1/2 lupus and scleroderma data during June 2026 EULAR Congress

PHILADELPHIA, May 14, 2026 (GLOBE NEWSWIRE) -- Cabaletta Bio, Inc. (Nasdaq: CABA), a late-stage clinical biotechnology company focused on developing and launching curative targeted cell therapies designed specifically for patients with autoimmune diseases, today reported financial results for the first quarter ended March 31, 2026, and provided a business update.

"Since January, while advancing our myositis pivotal trial and planning to initiate a second pivotal indication, we announced that we have signed a long-term commercial supply agreement with Cellares which provides the potential to produce rese-cel for thousands of patients per year at among the lowest cost of goods in the industry with minimal capital investment. In addition, today we are presenting data at ASGCT demonstrating that without preconditioning, even the lowest dose of rese-cel demonstrated compelling drug-free clinical responses in half of the pemphigus vulgaris patients through 6-months of follow-up," said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. "Later this quarter, we expect to announce initial data from the lowest dose cohort of lupus patients dosed without preconditioning. In the second half of 2026, we expect to report longer-term, PC-free rese-cel data from the lowest dose RESET-PV and RESET-SLE cohorts as well as data from patients treated with a higher PC-free dose of rese-cel. Bolstered by our recent oversubscribed financing, we believe we are well-positioned to advance rese-cel to BLA submission and potential commercial launch while continuing to differentiate and deliver rese-cel to autoimmune disease patients at scale."

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 after discontinuation of all immunomodulators, 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.

- **6-to-9-month rese-cel data in the lowest dose cohort without preconditioning from RESET-PV and initial clinical experience with Cellares-manufactured rese-cel being presented at the ASGCT 2026 Annual Meeting:** Today, at the American Society of Gene & Cell Therapy (ASGCT) 2026 Annual Meeting, and further detailed in a separate press release issued today, Cabaletta is presenting clinical and translational data from four patients in the lowest PC-free dose cohort in RESET-PV. In addition, the initial clinical experience with Cellares-manufactured rese-cel, based on two evaluable patients, demonstrated CAR T cell expansion and B cell depletion at similar magnitudes and on similar timeframes relative to rese-cel manufactured by current clinical supply partners.

- **Commercial supply capabilities expanded to build toward long-term, industrialized manufacturing using Cellares' automated platforms:** In April 2026, Cabaletta and Cellares announced a 10-year commercial supply agreement for rese-cel using Cellares' automated Cell Shuttle™ in addition to future planned implementation of Cellares' Cell Q™ platform. The Companies believe Cellares' automated platforms for manufacturing and quality control release can enable flexible, low-cost scaling of commercial production of rese-cel to thousands of batches per year at a per batch cost believed to be among the lowest in the industry for autologous cell therapy production. The agreement builds on the Companies' ongoing collaboration since 2023 to automate and industrialize the manufacturing of rese-cel.

- **Registrational RESET-Myositis trial advancing and updates on registrational trial designs anticipated in 2026:** Patient enrollment is progressing well in the registrational, 17-patient, single-arm dermatomyositis (DM) and antisynthetase syndrome (ASyS) cohort in RESET-Myositis. The cohort features 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. In addition, Cabaletta anticipates providing an update regarding registrational trial designs for RESET-SSc™ in 1H26 and potentially for RESET-MG™ in mid-2026.

- **Longer-term PC-free data at lowest dose and data at higher PC-free doses expected in 2H26:** Cabaletta plans to share longer-term rese-cel data from the PC-free cohorts in RESET-PV and RESET-SLE at the lowest dose in 2H26. In addition, the Company expects to present data from higher dose patients throughout 2026.

- **Complete Phase 1/2 cohort data from RESET-MG shared at AAN Annual Meeting:** In April 2026, Cabaletta presented complete Phase 1/2 cohort data from RESET-MG at the American Academy of Neurology (AAN) Annual Meeting. Across 7 acetylcholine

receptor (AChR)-positive and 6 AChR-negative patients who were evaluable, rese-cel exhibited a generally favorable risk-benefit profile with predictable peak expansion and associated B cell depletion. After discontinuation of immunomodulators, 5 AChR-positive and 5 AChR-negative patients experienced clinically meaningful improvement on the Myasthenia Gravis Activities of Daily Living score.

Upcoming Scientific Presentations & Symposia

Cabaletta expects to present multiple oral and poster presentations and to feature an abstract publication on rese-cel at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress, being held from June 3-6, 2026, in London, UK. Details are as follows:

- **RESET-SLE (POS0698):** Complete Phase 1/2 cohort data with preconditioning. Poster view presentation starting at 9:30 a.m. BST on Thursday, June 4, 2026.

- **RESET-Myositis (OPO170):** Longer-term follow-up from Phase 1/2 patients in the DM and ASyS cohorts. Oral abstract presentation starting at 9:15 a.m. BST on Thursday, June 4, 2026.

- **RESET-SSc:** Complete Phase 1/2 cohort data will be presented at a company-sponsored satellite symposium starting at 5:30 p.m. BST on Thursday, June 4, 2026.

- **RESET development program (POS0351):** Translational data from across several Phase 1/2 cohorts. Poster tour presentation starting at 10:39 a.m. BST on Saturday, June 6, 2026.

Additional information can be accessed on the website of theEULAR 2026 Congress. Presentation materials will be made available on the Posters & Publications section of the Company's website following their presentation.

Corporate Updates

- **Appointment of Francisco Ramírez-Valle, M.D., Ph.D., to Scientific Advisory Board:** In May 2026, Cabaletta announced the appointment of Dr. Ramírez-Valle to its Scientific Advisory Board. Dr. Ramírez-Valle currently serves as Senior Vice President, Immunology Research at Eli Lilly and Company where he leads the discovery and early development of its immunology portfolio. He has over two decades of experience as a physician-scientist driving medical research, translational development and clinical development across all stages of preclinical research, human clinical trials and biomarker development.

- **Raised $150 million in gross proceeds from registered direct offering:** In May 2026, Cabaletta closed an underwritten registered direct offering, which included participation from Bain Capital Life Sciences, Adage Capital Management, Cormorant Asset Management and other existing investors, multiple new mutual and sovereign wealth funds and Eli Lilly and Company. The gross proceeds from the offering were approximately $150 million.

Upcoming Investor Events

Cabaletta plans to participate in the following upcoming investor conferences:

- **H.C. Wainwright 4th Annual BioConnect Investor Conference at NASDAQ:** Fireside chat at 4:00 p.m. ET on Tuesday, May 19, 2026, in New York, NY.
- **Jefferies Global Healthcare Conference in New York:** Fireside chat at 7:35 a.m. ET on Wednesday, June 3, 2026, in New York, NY.
- **Goldman Sachs 47th Annual Global Healthcare Conference:** Fireside chat at 10:00 a.m. ET on Monday, June 8, 2026, in Miami, FL.

The fireside chats will be available on the News and Events section of the Company's website at www.cabalettabio.com. Replays will be available for at least 30 days.

First Quarter 2026 Financial Results

- Research and development expenses were $37.4 million for the three months ended March 31, 2026, compared to $29.0 million for the same period in 2025.
- General and administrative expenses were $6.9 million for the three months ended March 31, 2026, compared to $8.1 million for the same period in 2025.
- As of March 31, 2026, Cabaletta had cash, cash equivalents and short-term investments of $116.6 million, compared to $133.6 million as of December 31, 2025. The Company expects that its cash position as of March 31, 2026, along with cash raised from the May 2026 registered direct offering, will enable it to fund its operating plan into mid-2027.

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a late-stage clinical biotechnology company focused on developing and launching 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 curative targeted cell therapies 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 and acceptance of registrational designs related thereto and a BLA for rese-cel in myositis; the 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 of the 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 and expectations regarding the timing and results of clinical data from patients treated with rese-cel without preconditioning, including initial data from the lowest dose RESET-SLE cohort, longer-term data from the RESET-PV and RESET-SLE PC-free cohorts at the lowest dose and data from patients treated with a higher PC-free dose of rese-cel; Cabaletta's plans to announce additional clinical data from the RESET trials throughout 2026, including complete Phase 1/2 data to be presented from the RESET-SSc and RESET-SLE trials evaluating rese-cel with preconditioning; Cabaletta's plans to advance rese-cel to potential commercial launch; Cabaletta's plans to implement automated manufacturing of rese-cel with Cellares' Cell Shuttle and future plans to implement Cellares' Cell Q platform, including the timing of initial translational data and longer-term clinical data from patients receiving Cellares-manufactured rese-cel and its expectation that such platforms can enable scalability to produce rese-cel for thousands of patients per year with minimal capital investment; the anticipated benefits of the 10-year commercial supply agreement with Cellares, including expectations regarding manufacturing cost efficiency, competitive per batch cost for autologous cell therapy production, and minimal capital investment; and Cabaletta's use of capital, expense and other financial results in the future and its ability to fund operations into mid-2027.

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, Fast Track Designation and Regenerative Medicine Advanced Therapy 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 March 31,	
	2026	**2025**
	Unaudited	
Operating expenses:		
Research and development	$ 37,353	$ 29,018
General and administrative	6,943	8,118
Total operating expenses	44,296	37,136
Loss from operations	(44,296)	(37,136)
Other income (expense):		
Interest income	1,076	1,487
Interest expense	(636)	(294)
Other income, net	341	—
Net loss	$ (43,515)	$ (35,943)
Net loss per common stock share, basic and diluted	$ (0.39)	$ (0.71)

Selected Balance Sheet Data

	March 31, 2026	December 31, 2025
	Unaudited	
Cash, cash equivalents and short-term investments	$ 116,635	$ 133,599
Total assets	148,146	165,083
Total liabilities	44,841	53,032
Total stockholders' equity	103,305	112,051

Contacts:

Anup Marda
Chief Financial Officer
investors@cabalettabio.com

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Source: Cabaletta Bio