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): August 13, 2026

CABALETTA BIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39103**	**82-1685768**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2929 Arch Street **Suite 600** **Philadelphia, Pennsylvania**	**19104**
(Address of Principal Executive Offices)	**(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 August 13, 2026, Cabaletta Bio, Inc. (the "Company") announced its financial results for the second quarter ended June 30, 2026. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 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 of 1933, as amended, 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 August 13, 2026, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

SIGNATURE

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

CABALETTA BIO, INC.

Date: August 13, 2026

By: /s/ Steven Nichtberger

Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 99.1

Cabaletta Bio®

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

Registrational RESET-Myositis® clinical data on track to be reported in mid-2027 to support 2H27 BLA submission for rese-cel

Juvenile myositis Phase 1/2 data expected to be submitted with BLA to support potential FDA Priority Review Voucher

Registrational RESET-SSc® enrollment in approximately 25 patients with SSc-associated interstitial lung disease anticipated to initiate in 4Q26

PC-free approach being incorporated in RESET-MG® based on emerging insights from PC-free RESET-SLE® and RESET-PV® cohorts and previously reported Phase 1/2 clinical data

Pursuing expansion of outpatient dosing option for rese-cel within the RESET™ clinical development program based in part on favorable safety data reported at EULAR 2026

ElevateBio selected as second CDMO for clinical and commercial manufacturing of rese-cel

PHILADELPHIA, Aug. 13, 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 second quarter ended June 30, 2026, and provided a business update.

“A single infusion of rese-cel has demonstrated the potential to deliver deep, clinical responses after discontinuation of all immunomodulators with up to 1.5 years of follow-up as reported in the most recent Phase 1/2 clinical experience. Continued expansion of the outpatient dosing option with rese-cel remains a top priority, and we believe the reported safety profile supports its incorporation across the RESET clinical development program,” said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “Additionally, we view the product design and development characteristics of rese-cel, including the use of a fully-human CAR construct, weight-based dosing, and a well-characterized manufacturing process, to have contributed to the compelling clinical outcomes reported in adult and juvenile patients across multiple autoimmune diseases. As we progress rese-cel through and into registrational trials for myositis and systemic sclerosis, respectively, we are also particularly encouraged by the reported PC-free data in lupus and PV patients which have prompted us to incorporate the PC-free approach in RESET-MG.”

Recent Operational Highlights and Anticipated Upcoming Milestones

Resecabtagene autoleucel (rese-cel) for autoimmune diseases
Cabaletta is advancing rese-cel as an investigational CAR T cell therapy designed to reset the immune system in patients living with autoimmune diseases. Following a single, weight-based intravenous infusion after discontinuation of immunomodulators, rese-cel has shown the ability

to deliver an immune system reset in treated patients across multiple autoimmune diseases, leading to compelling clinical outcomes that have persisted over time. Cabaletta is evaluating rese-cel across the RESET (REstoring SElf-Tolerance) clinical development program, which includes multiple ongoing company-sponsored trials in rheumatology, neurology, and dermatology with disease-specific cohorts designed to evolve directly into registrational studies. Cabaletta is also advancing a program of innovations to broaden and deepen the treatment potential of rese-cel across autoimmune diseases.

Registrational RESET-Myositis data on track for mid-2027 to support first potential BLA submission for rese-cel in 2H27

- Cabaletta continues to anticipate reporting data from the registrational, 17-patient dermatomyositis (DM) and antisynthetase syndrome (ASyS) cohort in mid-2027, including 14 adult DM patients and 3 adult ASyS patients. If successful, Cabaletta plans to submit its first Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in 2H27, inclusive of data from the registrational cohort and the juvenile cohort which may facilitate the potential to be granted a Priority Review Voucher.
- At the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress, Cabaletta presented Phase 1/2 data demonstrating that 80% (8/10) of evaluable adult DM and ASyS patients would have met the primary endpoint of the registrational cohort, with all DM responders maintaining their responses through up to 1.5 years of follow-up. Cabaletta also reported that the first juvenile DM patient achieved an immunomodulator-free moderate Total Improvement Score response at 16 weeks, which was maintained through latest follow-up at 32 weeks.
- Across all 17 RESET-Myositis Phase 1/2 patients reported at EULAR 2026, 100% experienced no or Grade 1 (fever) cytokine release syndrome (CRS) and none experienced immune effector cell-associated neurotoxicity syndrome (ICANS), reinforcing a safety profile supportive of the outpatient dosing option already incorporated in the trial.

SSc-associated ILD selected as second registrational cohort to initiate in 4Q26

- Based on complete RESET-SSc Phase 1/2 cohort data and FDA feedback, Cabaletta is preparing to conduct a single-arm registrational study in a new cohort of approximately 25 patients with systemic sclerosis (SSc)-associated interstitial lung disease (ILD) using a forced vital capacity-based primary endpoint at 52 weeks. Cabaletta anticipates initiating this study in 4Q26.
- Updated data from RESET-SSc presented at the EULAR 2026 Congress demonstrated that patients showed overall improvement in skin and improvement in lung disease activity, achieving clinical responses while off immunomodulators and off or tapering steroids that appeared to increase in magnitude with longer follow-up.

PC-free approach being incorporated in RESET-MG and enrolling in higher-dose cohorts in RESET-PV and RESET-SLE

- Based on complete RESET-MG Phase 1/2 cohort data shared at the American Academy of Neurology Annual Meeting in April 2026 and emerging insights from the broader preconditioning (PC)-free program for rese-cel, Cabaletta is incorporating dose exploration with PC-free rese-cel in RESET-MG. In addition, rese-cel was granted Regenerative Medicine Advanced Therapy designation by the FDA for the treatment of generalized myasthenia gravis, building on this designation already granted to rese-cel as a potential treatment for myositis, systemic sclerosis, and lupus.

- Cabaletta presented PC-free data from RESET-PV at the American Society of Gene & Cell Therapy (ASGCT) 2026 Annual Meeting, with findings published in *Blood*, and from RESET-SLE at the EULAR 2026 Congress. Across both trials, rese-cel exhibited a predictable translational profile consistent with observations in patients treated with rese-cel and preconditioning. Based on the reported clinical findings, Cabaletta believes the lowest dose of rese-cel may represent a threshold dose in both trials and is advancing higher-dose cohorts in each trial.

Manufacturing partnerships expanded for long-term supply chain resiliency at scale

- Cabaletta has partnered with ElevateBio as an additional contract development and manufacturing organization (CDMO) partner alongside Lonza, adding capacity and supply chain security to support the anticipated scale of demand for rese-cel across autoimmune indications. Cabaletta expects ElevateBio and Lonza to support the transition from clinical to commercial supply using our substantially closed and partially automated process with increased capacity that was implemented prior to registrational evaluation of rese-cel.
- As part of its automated manufacturing strategy, Cabaletta announced a 10-year commercial supply agreement with Cellares in April 2026. The agreement enables Cabaletta to leverage Cellares' automated manufacturing capabilities to supply thousands of rese-cel batches per year with minimal capital investment and at a per batch cost anticipated to be among the lowest in the industry for autologous cell therapy production. At ASGCT 2026, translational data were presented demonstrating that rese-cel manufactured using the Cellares Cell Shuttle™ platform produces comparable CAR T cell expansion and B cell depletion kinetics relative to current clinical manufacturing processes, providing further proof of concept in addition to product comparability data for the Cellares automated manufacturing approach.

Second Quarter 2026 Financial Results

- Research and development expenses were $44.4 million for the three months ended June 30, 2026, compared to $37.6 million for the same period in 2025.
- General and administrative expenses were $7.6 million for the three months ended June 30, 2026, compared to $8.3 million for the same period in 2025.
- As of June 30, 2026, Cabaletta had cash, cash equivalents, and short-term investments of approximately $225.1 million, inclusive of net proceeds from the May 2026 registered direct offering, compared to $133.6 million as of December 31, 2025. The Company expects that its cash position as of June 30, 2026, 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. Cabaletta's lead product candidate, rese-cel, is an investigational 4-1BB-containing fully human CD19-CAR T cell therapy being advanced across the RESET™ (REstoring SElf-Tolerance) clinical development program spanning multiple therapeutic areas, including rheumatology, neurology and dermatology. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA. For more information, 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; Cabaletta's expectations regarding the timing of topline data from the registrational DM/ASyS cohort in mid-2027 and its plans to submit a BLA for rese-cel in myositis, inclusive of adult and juvenile DM data, in 2H27; Cabaletta's expectations regarding the potential eligibility for a Priority Review Voucher based on Rare Pediatric Disease Designation for juvenile DM; Cabaletta's plans regarding the initiation of a SSc-associated ILD registrational program in 4Q26; 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 advancement of 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, trial design and timing of 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; Cabaletta’s plans to generate and report PC-free dose-ranging data across multiple autoimmune indications; Cabaletta's expectations regarding the safety profile of rese-cel and its belief that such profile supports outpatient administration; Cabaletta's plans to expand the outpatient dosing option across the RESET clinical development program; Cabaletta's plans to advance rese-cel to potential commercial launch; Cabaletta's expectations regarding its manufacturing strategies, including the anticipated transition from clinical to commercial supply and plans to implement automated manufacturing of rese-cel with Cellares; the anticipated benefits of the 10-year commercial supply agreement with Cellares; 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 preclinical or clinical data, including signs of biologic activity or clinical response, may not be predictive of long-term results or translate across programs; 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 Cabaletta seeks to achieve with rese-cel; risks that modifications to trial design or approach may not have the intended benefits and that the trial design may need to be further modified; risks related to clinical trial site activation, delays in enrollment generally or enrollment rates that are lower than expected; delays related to assessment of clinical trial results; risks related to unexpected safety or efficacy data observed during clinical studies; risks related to volatile market and economic conditions and public health crises; Cabaletta’s ability to retain and recognize the intended incentives conferred by Orphan Drug Designation, Fast Track Designation, 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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
	Unaudited		Unaudited	
Operating expenses:				
Research and development	$ 44,430	$ 37,638	$ 81,783	$ 66,656
General and administrative	7,591	8,268	14,534	16,386
Total operating expenses	52,021	45,906	96,317	83,042
Loss from operations	(52,021)	(45,906)	(96,317)	(83,042)
Other income (expense):				
Interest income	1,604	1,410	2,680	2,897
Interest expense	(517)	(571)	(1,153)	(865)
Other income (expense), net	(84)	(61)	257	(61)
Net loss	$ (51,018)	$ (45,128)	$ (94,533)	$ (81,071)
Net loss per common stock share, basic and diluted	$ (0.34)	$ (0.73)	$ (0.72)	$ (1.44)

Selected Balance Sheet Data

	June 30, 2026	December 31, 2025
	Unaudited	
Cash, cash equivalents and short-term investments	$ 225,101	$ 133,599
Total assets	256,728	165,083
Total liabilities	46,135	53,032
Total stockholders' equity	210,593	112,051

Contacts
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