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 07, 2025

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 7, 2025, Cabaletta Bio, Inc. ("Cabaletta" or the "Company") announced its financial results for the second quarter ended June 30, 2025. 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 7, 2025, 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 7, 2025

By: /s/ Steven Nichtberger

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

Exhibit 99.1

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

– Registrational cohort enrollment in RESET-Myositis™ trial on track to start in 2H25 with anticipated 2027 BLA submission for rese-cel in myositis –

– Five disease-specific cohorts fully enrolled in the RESET™ clinical development program from over 70 clinical sites as of July 31, 2025, with expansion phase enrollment continuing –

– FDA meetings to align on the next wave of registrational cohorts for rese-cel anticipated in 3Q25 for lupus, 4Q25 for systemic sclerosis and 1H26 for myasthenia gravis –

– Rese-cel clinical data presented at the EULAR 2025 Congress reinforce compelling clinical responses with nearly all patients off immunomodulatory medications and steroids; favorable risk-benefit profile observed across myositis, lupus and systemic sclerosis patients –

– Closed $100 million public offering to support late clinical-stage development and commercial readiness activities for rese-cel; cash runway extended into 2H26 –

PHILADELPHIA, Aug. 7, 2025 -- 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 second quarter ended June 30, 2025, and provided a business update.

“We achieved significant progress advancing rese-cel in the first half of 2025, including aligning with the FDA on a registrational pathway for rese-cel in myositis to support an anticipated 2027 first BLA submission. We also presented new data that reinforce the therapeutic potential of rese-cel across several autoimmune diseases,” said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “As our early clinical data are emerging, enrollment in dermatomyositis, scleroderma and myasthenia gravis has been particularly robust. We look forward to building on this momentum by initiating the myositis registrational program, obtaining regulatory alignment on registrational pathways for two additional indications this year and presenting new clinical data at multiple scientific meetings in the second half of 2025, including complete Phase 1/2 data from RESET-Myositis as well as initial clinical data from RESET-PV™ evaluating rese-cel without pre-conditioning.”

Recent Operational Highlights and Upcoming Anticipated Milestones

Rese-cel: Rese-cel (resecabtagene 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

- **New clinical and translational data presented at the EULAR 2025 Congress:** In June 2025, Cabaletta presented new clinical and translational data from 18 evaluable patients in the ongoing RESET-Myositis, RESET-SLE™ and RESET-SSc™ trials in three oral presentations at the EULAR 2025 Congress. The data supported the ability of rese-cel to generate deep B cell depletion and compelling clinical responses in these patients, with nearly all patients off immunomodulators and steroids through the follow-up period.

- **On track to initiate enrollment in myositis registrational cohorts:** Cabaletta plans to initiate enrollment in two open-label, single-arm, registrational myositis cohorts consisting of approximately 15 patients each in the second half of 2025.

- **Upcoming anticipated clinical data presentations in 2025 and 2026:** In the second half of 2025, Cabaletta plans to present complete Phase 1/2 clinical data from the RESET-Myositis trial, initial dose data from the RESET-PV trial, which is evaluating rese-cel without preconditioning in patients with pemphigus vulgaris (PV), and initial clinical data from the RESET-MG™ trial. Additionally, Cabaletta expects to present complete Phase 1/2 clinical data from the RESET-SLE and RESET-SSc trials in the first half of 2026.

Regulatory

- **First BLA submission planned in 2027 for myositis following FDA alignment on key registrational design elements:** In May 2025, Cabaletta announced alignment with the U.S. Food and Drug Administration (FDA) on key design elements for two registrational cohorts in the RESET-Myositis trial. The cohort comprised of patients with dermatomyositis or antisynthetase syndrome represents about 85% of the myositis population, while the IMNM cohort represents about 15%. The two cohorts are independent of each other with regards to regulatory considerations, although as agreed with FDA, safety data from all rese-cel patients will be used to support the Biologics License Application (BLA). The Company plans to submit its first BLA for rese-cel in myositis in 2027 based on either cohort, if successful.

- **Additional regulatory discussions planned with FDA to align on additional registrational cohort designs:** Cabaletta plans to meet with the FDA to align on key registrational design elements for the RESET-SLE trial in 3Q25, the RESET-SSc trial in 4Q25 and the RESET-MG trial in 1H26.

Manufacturing

- **Advancing CMC commercial supply readiness and innovation activities:** To support commercial supply readiness, Cabaletta has been advancing BLA-enabling activities both lentiviral vector process and cellular drug product process. The Oxford Biomedica lentiviral process and the commercial drug product process, which has been transferred to Lonza, will be used for initiating registrational enrollment.

Corporate Updates

- In June 2025, Cabaletta closed an underwritten public offering consisting of shares of its common stock, pre-funded warrants and accompanying common stock warrants. The net proceeds from the offering were approximately $94 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company.

Second Quarter 2025 Financial Results

- Research and development expenses were $37.6 million for the three months ended June 30, 2025, compared to $23.4 million for the same period in 2024.

- General and administrative expenses were $8.3 million for the three months ended June 30, 2025, compared to $6.9 million for the same period in 2024.

- As of June 30, 2025, Cabaletta had cash, cash equivalents and short-term investments of $194.7 million, compared to $164.0 million as of December 31, 2024. The Company expects that its cash position as of June 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 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 reinforces the therapeutic potential of rese-cel across several autoimmune diseases; the clinical

significance of the clinical data read-out at upcoming scientific meetings and timing thereof; Cabaletta's belief that it has obtained alignment with FDA on the registrational path for rese-cel; 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 and gMG and advancement of the RESET-PV and RESET-MS trials, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; Cabaletta's ability to expand its clinical supply for registrational trial(s) across the RESET clinical development program as well as to expand its manufacturing options for rese-cel; Cabaletta's ability to increase enrollment in its US and Europe clinical networks; Cabaletta's plans to initiate enrollment in two open-label, single-arm, registrational myositis cohorts consisting of approximately 15 patients each in the second half of 2025; Cabaletta's plans to meet with the FDA to discuss registrational cohorts for rese-cel and the timing thereof; Cabaletta's expectations surrounding the anticipated initiation of three new registrational cohorts, potential BLA submission and timing thereof; 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 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	unaudited		unaudited	
Operating expenses:				
Research and development	$ 37,638	$ 23,427	$ 66,656	$ 45,381
General and administrative	8,268	6,852	16,386	12,929
Total operating expenses	45,906	30,279	83,042	58,310
Loss from operations	(45,906)	(30,279)	(83,042)	(58,310)
Other income:				
Interest income	1,410	2,677	2,897	5,661
Interest expense	(571)	—	(865)	—
Other expense	(61)	—	(61)	—
Net loss	$ (45,128)	$ (27,602)	$ (81,071)	$ (52,649)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.73)	$ (0.56)	$ (1.44)	$ (1.07)

Selected Balance Sheet Data

	June 30, 2025	December 31, 2024
	(unaudited)	
Cash, cash equivalents and investments	$ 194,682	$ 163,962
Total assets	224,500	185,046
Total liabilities	46,019	32,711
Total stockholders' equity	178,481	152,335

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