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CABALETTA BIO, INC.

FORM 8-K
(Current report filing)

Filed 11/05/26 for the Period Ending 11/05/26

Address	2929 ARCH STREET SUITE 600 PHILADELPHIA, PA, 19104
Telephone	(267) 759-3100
CIK	0001759138
Symbol	CABA
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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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): November 05, 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 November 5, 2026, Cabaletta Bio, Inc. (the "Company") announced its financial results for the third quarter ended September 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 November 5, 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: November 5, 2026

By: /s/ Steven Nichtberger

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

Exhibit 99.1

Cabaletta Bio®

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

RESET-Myositis® registrational adult topline results anticipated in 2H27 with BLA submission in 1Q28, including Phase 1/2 juvenile dermatomyositis data for potential PRV eligibility and Phase 1/2 adult durability data

Immunomodulator-free durability data from the complete Phase 1/2 dermatomyositis cohort at one year and from the complete Phase 1/2 lupus nephritis cohort with follow-up as long as two years as well as updated safety data from the RESET™ program with preconditioning to be presented during ACR Convergence 2026

RESET-SSc® registrational cohort initiated in systemic sclerosis patients with interstitial lung disease including endpoints evaluating improvement of lung function and overall disease

PC-free program advancing with maturing data expected to inform 1H27 go-forward clinical development plans

Operational runway extended into 1Q28 with $299.4 million cash position as of September 30, 2026

PHILADELPHIA, Nov. 05, 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 third quarter ended September 30, 2026, and provided a business update.

“We are encouraged by the favorable benefit-risk profile observed with rese-cel to date as we made deliberate choices, including construct design, standard and well-characterized manufacturing, and weight-based dosing, from the outset of its development to prioritize patient safety,” said Steven Nichtberger, M.D., Chief Executive Officer of Cabaletta. “We are now seeing increased enrollment and screening activity, with multiple patients enrolled in the past few weeks in the registrational adult myositis study, after a slower period in 3Q26 that we believe was influenced by patient and physician caution following recently reported safety events from others in the field. Additionally, we are excited by progress in our juvenile dermatomyositis program and expect to have a robust dataset from these patients to include with our planned BLA submission in myositis in the first quarter of 2028, potentially enabling our eligibility for a Priority Review Voucher. We also initiated our second registrational study to evaluate the ability of rese-cel to improve lung function and overall disease in systemic sclerosis, a patient population with one of the highest mortality rates among rheumatological conditions. In parallel, our PC-free program continues to build toward a dataset that will guide our path forward on the optimal dose and development strategy, which we plan to announce in the first half of 2027.”

Recent Operational Highlights and Anticipated Upcoming Milestones

Resecabtagene autoleucel (rese-cel) for autoimmune diseases
Rese-cel is an investigational chimeric antigen receptor (CAR) T cell therapy designed to achieve a potential immune reset 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 reset, leading to clinical responses that have sustained over time. Cabaletta is evaluating rese-cel across the REstoring SElf-Tolerance (RESET™) clinical development program, which includes multiple single-arm, 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.

RESET-Myositis registrational topline results expected 2H27 to support planned BLA submission in 1Q28

- The registrational, 17-patient dermatomyositis (DM) and antisynthetase syndrome (ASyS) cohort, which incorporates an outpatient dosing option, is expected to deliver topline results in the second half of 2027 to support a planned Biologics License Application (BLA) submission in myositis to the U.S. Food and Drug Administration (FDA) in the first quarter of 2028.
- Based on a recent Type B regulatory interaction with the FDA, Cabaletta has the ability to include multi-year Phase 1/2 myositis durability data to support the planned BLA submission. Cabaletta will present one-year clinical data from the complete Phase 1/2 DM cohort at the upcoming American College of Rheumatology (ACR) Convergence 2026 annual meeting. Cabaletta expects to have three-year durability data from some Phase 1/2 patients at the time of potential launch.
- The Phase 1/2 juvenile myositis cohort, which is focused on juvenile dermatomyositis (JDM) and incorporates an outpatient dosing option, continues to be open for patient enrollment. As part of its planned BLA submission in myositis, Cabaletta plans to include JDM data from this cohort to support a potential pediatric indication, enabling potential eligibility for a Priority Review Voucher (PRV).

RESET-SSc registrational cohort initiated and open for patient enrollment

- Cabaletta initiated the registrational, approximately 25-patient cohort in systemic sclerosis patients with a focus on interstitial lung disease and an outpatient dosing option. These patients have one of the highest mortality rates among rheumatological conditions and there are currently no FDA-approved therapies that can improve lung function in these patients. The primary endpoint is designed to measure the mean change from baseline in percent-predicted forced vital capacity (FVC) without any immunomodulators or anti-fibrotic medications and on no or a low-dose of steroids.

Prioritized PC-free trials generating dose optimization insights for 1H27 go-forward clinical development plans

- RESET-SLE® continues to be open for enrollment of lupus patients and is currently evaluating higher-dose, preconditioning-free (PC-free) rese-cel. Additionally, RESET-SLE has incorporated adolescent patient enrollment in the Phase 1/2 cohorts with preconditioning.
- RESET-MG® has initiated PC-free rese-cel dose exploration and is open for enrollment of myasthenia gravis patients.
- RESET-PV® continues to be open for enrollment of pemphigus vulgaris patients at higher-dose, PC-free rese-cel.

Recent external scientific presentations

- At the European Society of Gene and Cell Therapy 2026 Annual Meeting, Cabaletta presented a poster presentation titled, “Differential macrophage responses to CAR T cell produced cytokines across autoimmune diseases may confer differential risk among indications.” Data in the presentation indicate the potential relationship between the pro-inflammatory activation of monocyte-derived macrophages in different autoimmune diseases, with a focus on Phase 1/2 dermatomyositis and systemic sclerosis patients treated with rese-cel, and the observation of adverse safety events in autoimmune disease patients. In addition, longer-term Phase 1/2 clinical efficacy data in systemic sclerosis patients treated with rese-cel were shared. At one year and off immunomodulators, the five patients with interstitial lung disease achieved a mean percent-predicted FVC improvement of approximately 9% and, among all systemic sclerosis patients with at least one year of follow-up, six of seven (86%) patients achieved rCRISS-25.
- At the American Association of Neuromuscular & Electrodiagnostic Medicine 2026 Annual Meeting, Cabaletta presented clinical and translational data from the first 14 RESET-MG patients treated with rese-cel and preconditioning. Rese-cel was generally well tolerated, with no cytokine release syndrome in 12 patients and no immune effector cell-associated neurotoxicity syndrome or immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome. At 24 weeks, patients who remained off immunomodulators (n=10) had a mean change from baseline of -7.9 on the Myasthenia Gravis Activities of Daily Living scale (MG-ADL) and -7.8 on the Quantitative Myasthenia Gravis score, and 10 of the 14 patients achieved a clinically meaningful MG-ADL improvement as of latest follow-up (median follow-up of 38 weeks) while off immunomodulators.

Upcoming presentations and Innovation Theater at ACR Convergence 2026

- Cabaletta will present an oral presentation (0902) on one-year clinical responses in dermatomyositis patients treated with rese-cel at 1:00 p.m. ET on Sunday, November 8, and three poster presentations (1222, 1673, 1728) on updated rese-cel clinical and safety data and the opportunity of CAR T cell therapy in autoimmune diseases from 10:30 a.m. – 12:30 p.m. ET on Monday, November 9.
- Cabaletta will host an industry-supported Innovation Theater titled, “Designed for Autoimmunity: Rese-cel and the RESET™ Clinical Program,” featuring David J. Chang, M.D., M.P.H., FACR, Chief Medical Officer of Cabaletta Bio, David L. Porter, M.D., Jodi Fisher Horowitz Professor of Leukemia Care Excellence and Director, Center for Cell Therapy and Transplant, University of Pennsylvania, and Dinesh Khanna, M.D., M.Sc., FACR, Frederick G. L. Huetwell Professor of Medicine and Director, University of Michigan Scleroderma Program, at 1:30 p.m. ET on Tuesday, November 10.

Third Quarter 2026 Financial Results

- Research and development expenses were $47.1 million for the three months ended September 30, 2026, compared to $39.8 million for the same period in 2025.
- General and administrative expenses were $7.6 million for the three months ended September 30, 2026, compared to $6.8 million for the same period in 2025.
- As of September 30, 2026, Cabaletta had cash and cash equivalents of approximately $299.4 million, inclusive of approximately $115.0 million from exercises of common stock warrants received between July 1, 2026, and the warrants’ expiration on September 12, 2026. The Company expects that its cash position as of September 30, 2026, will enable it to fund its operating plan into the first quarter of 2028.

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, resecabtagene autoleucel (rese-cel), is an investigational 4-1BB-containing fully human CD19-CAR T cell therapy being advanced across the REstoring SElf-Tolerance (RESET™) 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 results from the registrational DM/ASyS cohort in the second half of 2027 and its plans to submit a BLA for rese-cel in myositis, inclusive of adult and juvenile DM data, in 1Q28; Cabaletta's expectations regarding the inclusion of multi-year Phase 1/2 myositis durability data in its planned BLA submission based on its recent Type B regulatory interaction with the FDA; Cabaletta's expectations regarding the potential eligibility for a Priority Review Voucher based on a potential pediatric indication for juvenile DM; Cabaletta's plans and expectations regarding the registrational RESET-SSc cohort in systemic sclerosis-associated interstitial lung disease, including enrollment, trial design, and timing of data read-outs; 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, 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 dose optimization insights from its PC-free trials across multiple autoimmune indications and to announce go-forward clinical development plans in the first half of 2027; Cabaletta's expectations regarding the safety profile of rese-cel and its belief that such profile supports outpatient administration and Cabaletta's plans to expand the outpatient dosing option across the RESET clinical development program; and Cabaletta's use of capital, expense and other financial results in the future and its ability to fund its operating plan into the first quarter of 2028.

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	Unaudited		Unaudited	
Operating expenses:				
Research and development	$ 47,144	$ 39,824	$ 128,927	$ 106,480
General and administrative	7,563	6,764	22,097	23,150
Total operating expenses	54,707	46,588	151,024	129,630
Loss from operations	(54,707)	(46,588)	(151,024)	(129,630)
Other income (expense):				
Interest income	2,144	1,808	4,824	4,705
Interest expense	(511)	(584)	(1,664)	(1,449)
Other income, net	21	498	278	437
Net loss	$ (53,053)	$ (44,866)	$ (147,586)	$ (125,937)
Net loss per common stock share, basic and diluted	$ (0.28)	$ (0.44)	$ (0.98)	$ (1.75)

Selected Balance Sheet Data

	September 30, 2026	December 31, 2025
	Unaudited	
Cash, cash equivalents and short-term investments	$ 299,383	$ 133,599
Total assets	336,491	165,083
Total liabilities	52,572	53,032
Total stockholders' equity	283,919	112,051

Contacts
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