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): May 4, 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 8.01 Other Events.

Cabaletta intends to present new clinical and translational data from 4 refractory patients that receivedrese-cel at the lowest dose without preconditioning in the RESET-PV® (pemphigus vulgaris) trial at the American Society of Gene & Cell Therapy (ASGCT) 2026 Annual Meeting, being held on May 14, 2026. The RESET-PV trial is the first study within Cabaletta's RESET clinical development program to evaluaterese-cel without the use of cyclophosphamide and fludarabine as preconditioning agents.

Key clinical and translational insights from these 4 refractory patients who receivedrese-cel at the lowest dose without preconditioning and had follow-up between 24 and 36 weeks as of the data cut-off date of April 2, 2026, include:

- After discontinuing all immunomodulators, clear biologic and clinical activity was observed without preconditioning.
  - 2 of 4 patients demonstrated compelling clinical activity through 6 monthsfollow-up.
  - 3 of 4 patients remained off all immunomodulators and steroids as of the datacut-off.
  - Complete peripheral B cell elimination was observed in 3 of 4 patients.
  - On safety, cytokine release syndrome (CRS) was observed in 1 of 4 patients (Grade 1) and no immune effector cell-associated neurotoxicity syndrome (ICANS) was observed of any grade.
- Based on the safety profile observed at the lowest dose, multiple additional patients have been enrolled at a higher dose cohort in the RESET-PV trial and durability data at the higher dose is anticipated in the second half of 2026.
- In the RESET-SLE trial evaluating rese-cel without preconditioning in patients with lupus, the initial dose cohort is fully enrolled with initial data at the first dose anticipated in the first half of 2026.

Forward-Looking Statements

The information under this Item 8.01 contains "forward-looking statements" of Cabaletta 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 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; Cabaletta's ability to leverage its emerging clinical data and its efficient development strategy; the clinical significance of the clinical data read-out at upcoming scientific meetings and timing thereof; the clinical significance of clinical and translational data from the RESET-PV trial evaluating rese-cel without preconditioning, including the anticipated timing and results of additional dose cohorts; 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 theRESET-MS trial, including updates related to status, safety data, efficiency of clinical trial design and timing of data read-outs or otherwise; and Cabaletta's plans to incorporate a new dose-escalation cohort into the RESET-SLE trial and the status of enrollment in the initial dose cohort of the no preconditioning cohort in the RESET-SLE trial, with initial data at the first dose anticipated in the first half of 2026;

Any forward-looking statements in this Item 8.01 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 filings with the Securities and Exchange Commission. All information in this Item 8.01 is as of the date of this Current Report on Form 8-K, and the Company undertakes no duty to update this information unless required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

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: May 4, 2026

By: /s/ Steven Nichtberger

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