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

August 18, 2023
Date of Report (Date of earliest event reported)

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)**	**(I.R.S. Employer Identification No.)**

2929 Arch Street, Suite 600, Philadelphia, PA	**19104**
(Address of principal executive offices)	**(Zip Code)**

(267) 759-3100
(Registrant's telephone number, including area code)

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 7.01 Regulation FD Disclosure..

On August 22, 2023, Cabaletta Bio, Inc. (the "Company") issued a press release announcing the Company's expansion of its Good Manufacturing Practice ("GMP") Manufacturing Agreement with WuXi Advanced Therapies, Inc. ("WuXi ATU") to include CABA-201. A copy of this press release is furnished as Exhibit 99.1 to this report on Form 8-K.

The information contained in Item 7.01 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 8.01 Other Events.

On August 18, 2023, the Company entered into new work orders (the "Work Orders"), effective as of August 11, 2023 (the "Effective Date"), under the Company's existing Development, Manufacturing, and Testing Services Agreement with WuXi ATU dated as of January 11, 2021 ("WuXi Agreement"). Pursuant to the Work Orders, WuXi ATU will serve as one of the Company's cell processing manufacturing partners for the planned global clinical development of CABA-201 in multiple indications, including potential late-stage clinical trials and commercial readiness activities for CABA-201, in addition to WuXi ATU's current engagement for the MuSK-CAART Phase 1 clinical trial. WuXi ATU will convert the Company's current non-dedicated suite to a dedicated suite for GMP manufacturing for the Company's CABA-201 and MuSK-CAART programs (the "Dedicated Suite") for an initial term of eighteen (18) months with two eighteen (18) month extensions at the Company's sole option on six (6) months notice prior to the end of the term. In addition, the Company agreed to certain monthly minimum runs. In lieu of the existing $1.5 million termination fee under the terms of the WuXi Agreement, the Company would incur a $1.08 million termination fee if it terminates both the CABA-201 and MuSK-CAART Work Orders for any reason. The Company may terminate for convenience with six (6) months prior written notice, however, the Company may not terminate the Dedicated Suite without termination both MuSK-CAART and CABA-201 GMP run work orders. In lieu of the existing eighteen (18) month termination right for convenience under the WuXi Agreement, WuXi ATU may not terminate prior to fifty-four (54) months from the Effective Date.

The foregoing description of the terms of the WuXi Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the WuXi Agreement which was filed as Exhibit 10.34 to the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on March 16, 2023.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press release of Cabaletta Bio, Inc. dated August 22, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

SIGNATURE

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

CABALETTA BIO, INC.

Date: August 22, 2023

By: /s/ Steven Nichtberger
Steven Nichtberger, M.D.
President and Chief Executive Officer

Cabaletta Bio®

Cabaletta Bio and WuXi Advanced Therapies Announce Expansion of GMP Manufacturing Agreement to Include CABA-201

– Agreement expansion facilitates preparation for commercial readiness for CABA-201, enabling treatment of patients in multiple planned clinical trials with separate parallel cohorts –

– Partnership for CABA-201 builds on existing manufacturing agreement for clinical trial supply of MuSK-CAART for MusCAARTes™ trial –

PHILADELPHIA, August 22, 2023 – Cabaletta Bio, Inc. (Nasdaq: CABA), a clinical-stage biotechnology company focused on developing and launching the first curative targeted cell therapies for patients with autoimmune diseases, today announced that it has entered into certain work orders relating to Good Manufacturing Practice (GMP) manufacturing under its existing master services agreement with WuXi Advanced Therapies (WuXi ATU), a global Contract Testing, Development and Manufacturing Organization (CTDMO). As part of the agreement, WuXi ATU will serve as a cell processing manufacturing partner for the planned global clinical development of CABA-201 in multiple indications, including potential late-stage clinical trials and commercial readiness activities for CABA-201.

"We have had a successful collaboration with WuXi ATU over the past two years for the GMP compliant production of novel cell therapies. Based on this initial collaboration, we chose to expand our partnership to include WuXi ATU as a manufacturer for our CABA-201 clinical programs," said Gwendolyn Binder, Ph.D., President of Science and Technology of Cabaletta. "WuXi ATU's dedicated production capacity for CABA-201 supports our planned global expansion and commercial preparedness efforts and will enable us to dose patients in multiple clinical trials with separate parallel cohorts, while maintaining a capital-efficient manufacturing strategy."

Under the terms of the agreement, WuXi ATU will provide GMP manufacturing of CABA-201, a 4-1BB-containing fully human CD19-CAR T cell investigational therapy, to support any of Cabaletta's planned clinical trials, including the previously announced separate Phase 1/2 clinical trials of CABA-201 for the treatment of patients with systemic lupus erythematosus and idiopathic inflammatory myopathies, or myositis. In addition, WuXi ATU will continue to serve as the Company's cell processing manufacturing partner for the MusCAARTes™ Phase 1 clinical trial of MuSK-CAART.

"We are delighted to expand our partnership with Cabaletta to advance the development of CABA-201 for patients with autoimmune diseases," said David Y. H. Chang, Ph.D., President and Chief Technology Officer of WuXi ATU. "We look forward to applying our expertise in cell and gene therapy manufacturing to better support our customers to bring potentially life-saving treatments faster to patients in need."

About Cabaletta Bio

Cabaletta Bio (Nasdaq: CABA) is a clinical-stage biotechnology company focused on the discovery and development of engineered T cell therapies that have the potential to provide a deep and durable, perhaps curative, treatment for patients with autoimmune diseases. The CABA™ platform encompasses two strategies: the CARTA (chimeric antigen receptor T cells for autoimmunity) strategy, with CABA-201, a 4-1BB-containing fully human CD19-CAR T, as the lead product candidate being evaluated in systemic lupus erythematosus and myositis, and the CAART (chimeric autoantibody receptor T cells) strategy, with multiple clinical-stage candidates, including DSG3-CAART for mucosal pemphigus vulgaris and MuSK-CAART for MuSK myasthenia gravis. The expanding CABA™ platform is designed to develop potentially curative therapies that offer deep and durable responses for patients with a broad range of autoimmune diseases. Cabaletta Bio's headquarters and labs are located in Philadelphia, PA.

About WuXi Advanced Therapies (WuXi ATU)

As the advanced therapies business unit of WuXi AppTec, WuXi Advanced Therapies is a Contract Testing, Development and Manufacturing Organization (CTDMO) that offers integrated platforms to transform the discovery, development, testing, manufacturing, and commercialization of cell and gene therapies. Our services and solutions accelerate time to market and support customer programs around the world. For more information, please visit www.advancedtherapies.com.

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 its expectations regarding: Cabaletta's ability to capitalize on and the potential benefits of the expanded scope of its collaboration with WuXi ATU; Cabaletta's ability to grow its autoimmune-focused pipeline; its plans around CABA-201, including its ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner and advance the separate Phase 1/2 clinical trials of CABA-201 in each indication; the Company's business plans and objectives; the progress and results of its MusCAARTeś™ Phase 1 trial, including Cabaletta's ability to enroll the requisite number of patients, dose each dosing cohort in the intended manner, and progress the trial; the expectation that Cabaletta Bio may improve outcomes for patients suffering from systemic lupus erythematosus, myositis, MuSK-associated myasthenia gravis, or other autoimmune diseases as well as its expected therapeutic benefits; and the ability to accelerate Cabaletta's pipeline and develop meaningful therapies for patients, including in collaboration with academic and industry partners and the ability to optimize such collaborations on its development programs.

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 DSG3-CAART, MuSK-CAART and CABA-201; the risk that the results observed with the similarly-designed construct employed in the recent *Nature Medicine* publication, including due to the dosing regimen, are not indicative of the results we seek to achieve with CABA-201; risks related to clinical trial site activation or enrollment rates that are lower than expected; 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 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 press release is as of the date of the release, and Cabaletta undertakes no duty to update this information unless required by law.

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