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): June 27, 2024

COGENT BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38443**	**46-5308248**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

275 Wyman Street, 3rd Floor **Waltham, Massachusetts** **(Address of principal executive offices)**	**02451** **(Zip Code)**

Registrant's telephone number, including area code: (617) 945-5576

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, $0.001 Par Value	COGT	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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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.

Cogent Biosciences, Inc. (the "Company") announced today that it had a positive meeting with the U.S. Food and Drug Administration (the "FDA"), and that the Company reached alignment with the FDA on the Company's novel patient reported outcome measure, Mastocytosis Symptom Severity Daily Diary ("MS2D2"), for use in Part 2 of the Company's registration-directed SUMMIT clinical trial evaluating bezuclastinib in patients with Nonadvanced Systemic Mastocytosis.

The full text of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated June 27, 2024.
104	The cover page from the Company's Current Report on Form 8-K formatted in Inline XBRL.

SIGNATURES

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 hereunto duly authorized.

Date: June 27, 2024

COGENT BIOSCIENCES, INC.

By: /s/ Evan Kearns
Evan Kearns
Chief Legal Officer and Corporate Secretary

Cogent Biosciences Announces Positive FDA Meeting and Alignment on MS2D2, a Novel Patient Reported Outcome Measure for the SUMMIT trial

Enrollment in SUMMIT Part 2 remains on track for completion in Q2 2025 with top-line results expected by end of 2025

WALTHAM, Mass. and BOULDER, Colo., June 27, 2024 – Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced it has reached alignment with the U.S. Food and Drug Administration (FDA) on the Company's novel patient reported outcome measure, Mastocytosis Symptom Severity Daily Diary (MS2D2), for use in Part 2 of the registration-directed SUMMIT trial evaluating bezuclastinib in Nonadvanced Systemic Mastocytosis (NonAdvSM) patients.

"We recently completed a positive discussion with the FDA on the use of MS2D2 in our SUMMIT trial for Nonadvanced Systemic Mastocytosis patients," said Andrew Robbins, Cogent's President and Chief Executive Officer. "We remain on track to complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and report top-line results by year-end 2025."

Cogent's questionnaire, MS2D2, asks patients about their symptoms at baseline and measures the increase or decrease in those symptoms throughout the trial. A subset including the eleven most frequent and severe symptoms will form the basis of the total symptom score (TSS), which will be used to measure the primary endpoint of the SUMMIT Part 2 trial.

Bezuclastinib Clinical Development

Cogent remains on-track to complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and report top-line results by the end of 2025. The Company also remains on track to complete enrollment in the APEX study in patients with Advanced Systemic Mastocytosis (AdvSM) by the end of 2024 and report top-line results mid-2025. Enrollment continues in the Phase 3 registration-enabling PEAK study, which will include approximately 388 second-line, post imatinib patients with Gastrointestinal Stromal Tumors (GIST). Due to rapid enrollment, the Company expects PEAK enrollment to be completed in the third quarter of 2024 with top-line results expected by the end of 2025.

About Cogent Biosciences, Inc. Cogent Biosciences is a biotechnology company focused on developing precision therapies for genetically defined diseases. The most advanced clinical program, bezuclastinib, is a selective tyrosine kinase inhibitor that is designed to potently inhibit the KIT D816V mutation as well as other mutations in KIT exon 17. KIT D816V is responsible for driving systemic mastocytosis, a serious disease caused by unchecked proliferation of mast cells. Exon 17 mutations are also found in patients with advanced gastrointestinal stromal tumors (GIST), a type of cancer with strong dependence on oncogenic KIT signaling. In addition to bezuclastinib, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases initially targeting mutations in FGFR2, ErbB2 and PI3Kα. Cogent Biosciences is based in Waltham, MA and Boulder, CO. Visit our website for more information at www.cogentbio.com. Follow Cogent Biosciences on social media: X (formerly known as Twitter) and LinkedIn. Information that may be important to investors will be routinely posted on our website and X.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding: the expectation to complete enrollment in SUMMIT Part 2 in Q2 2025 and to report top-line results by the end of 2025, the expectation to complete enrollment in the APEX trial by the end of 2024 and to report top-line results mid-2025, the expectation to complete enrollment of approximately 388 GIST patients in the PEAK trial in the third quarter of 2024 and to report top-line results by the end of 2025 and the calculation of the total symptom score (TSS) that will be used to measure the primary endpoint of the SUMMIT Part 2 trial. The use of words such as, but not limited to, “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” and similar words expressions are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results, the rate of enrollment in our clinical trials and other future conditions. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. We may not actually achieve the forecasts or milestones disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption “Risk Factors” in Cogent’s most recent Quarterly Report on Form 10-Q filed with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither we, nor our affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date hereof.

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