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): September 3, 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 its Phase 3 PEAK clinical trial in patients with gastrointestinal stromal tumors ("GIST") has completed enrollment and advanced past the pre-planned interim futility analysis. The Company also announced that its Phase 2 SUMMIT clinical trial in patients with nonadvanced systemic mastocytosis ("NonAdvSM") is now expected to complete enrollment during the first quarter of 2025, approximately three months earlier than originally projected.

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 September 3, 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: September 3, 2024

COGENT BIOSCIENCES, INC.

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

Cogent Biosciences Announces Phase 3 PEAK Trial in Patients with Gastrointestinal Stromal Tumors (GIST) Has Completed Enrollment and Advanced Past Interim Futility Analysis

413 patients enrolled in PEAK Phase 3 GIST trial, exceeding enrollment target; top-line results expected by end of 2025

PEAK interim futility analysis completed with no changes to study

Registration-directed SUMMIT trial in NonAdvanced Systemic Mastocytosis (NonAdvSM) now on track to complete enrollment in Q1 2025; top-line results expected 2H 2025

WALTHAM, Mass. and BOULDER, Colo., September 3, 2024 - Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today provided several updates from the company's ongoing registration-directed clinical trials of its potential best-in-class KIT mutant inhibitor, bezuclastinib.

Patient enrollment is now complete in Cogent's Phase 3 PEAK trial evaluating bezuclastinib in combination with sunitinib for the treatment of patients with gastrointestinal stromal tumors (GIST). Based on strong global patient interest, a total of 413 patients were enrolled in the study. In addition, Cogent recently completed a pre-planned interim futility analysis, and the Independent Data Monitoring Committee (IDMC) recommended continuing the PEAK study without modification. This pre-specified analysis was based on an assessment of progression-free survival (PFS) as determined by independent central review and did not include the option for early stopping due to efficacy.

Separately, based on significant patient interest in the ongoing SUMMIT trial in nonadvanced systemic mastocytosis (NonAdvSM), Cogent also announced today that it expects to complete enrollment in this study during Q1 2025, approximately three months earlier than originally projected.

"We are excited to announce these important updates to the PEAK and SUMMIT studies today," said Andrew Robbins, Cogent's President and Chief Executive Officer. "Strong continued interest from patients around the world to participate in our bezuclastinib trials has allowed us to accelerate development and surpass our original enrollment timelines. Completing enrollment in our Phase 3 PEAK trial of bezuclastinib and sunitinib for second-line GIST patients several months ahead of schedule represents a significant milestone for the program and we are extremely grateful to the patients, families, caregivers, advocacy groups and clinical investigators for their participation in, and support of, the PEAK trial."

PEAK is a randomized, open-label, global Phase 3 clinical trial evaluating bezuclastinib in combination with sunitinib vs. sunitinib alone in GIST patients previously treated with imatinib. The primary endpoint of the trial is median progression free survival (mPFS). PEAK is a registration study intended to support a New Drug Application (NDA) in GIST.

SUMMIT is a randomized, blinded, global, registration-directed clinical trial evaluating bezuclastinib vs. placebo in NonAdvSM patients. The primary endpoint of the trial is mean improvement in patient symptoms measured at 24 weeks. SUMMIT is intended to be a registrational study designed to support a New Drug Application (NDA) in NonAdvSM.

Appointment of Darara Dibabu as Vice President of Marketing

In addition to the updates to PEAK and SUMMIT trials, Cogent announced today that Mr. Dibabu has joined Cogent as the VP of Marketing. Mr. Dibabu has 25 years of experience in the biopharmaceutical industry, most recently as the Global Brand Lead of TUKYSA at Pfizer and SeaGen, where he led the global launch and marketing strategy of the product for metastatic breast cancer patients. Previously, he served in various roles of increasing responsibility at Seagen, Bayer and Merck. Mr. Dibabu holds a bachelor's degree in Biology from the University of Southern California. In connection with Mr. Dibabu joining the company, he was granted an "inducement" equity award in accordance with Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market. The award was approved by the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, as an inducement material to Mr. Dibabu's employment. The award consists of nonqualified options to purchase 100,000 shares of Cogent common stock with a 10-year term, at an exercise price of $10.74 per share, and a 4-year vesting schedule with 25% vesting on the 1-year anniversary of Mr. Dibabu's employment and the remainder vesting in equal monthly installments over the subsequent 36 months, provided Mr. Dibabu's remains employed through each such vesting date.

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 report top-line results from the PEAK trial by the end of 2025, the expectation to complete enrollment in SUMMIT Part 2 in Q1 2025, three months earlier than originally projected, and to report top-line results in the second half of 2025, the potential for bezuclastinib to be a best-in-class KIT mutant inhibitor, the expectation for PEAK to support an NDA in GIST and the intention for SUMMIT to be a registrational study designed to support an NDA in NonAdvSM. 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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