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 3, 2023

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

On June 3, 2023, Cogent Biosciences, Inc. (the "Company") announced positive lead-in data from its ongoing Phase 3 PEAK trial evaluating the selective KIT D816V inhibitor bezuclastinib in patients with Gastrointestinal Stromal Tumors ("GIST") and presented the data results at the American Society of Clinical Oncology Annual Meeting in Chicago, IL.

PEAK Study Design

The PEAK study is a randomized, open-label, global, Phase 3 clinical trial evaluating bezuclastinib in combination with sunitinib in GIST patients previously treated with imatinib. As of the data cutoff date of March 29, 2023, 39 patients had been treated in Part 1, with 19 patients in Part 1a and 20 patients in Part 1b. Seven patients had received only imatinib as prior therapy, and 32 patients had received at least two prior tyrosine kinase inhibitor ("TKI") therapies.

Safety Data

As of the cutoff date of March 29, 2023, the combination of bezuclastinib and sunitinib was generally well-tolerated with an encouraging safety profile. The majority of treatment-emergent adverse events ("TEAEs") were low-grade and reversible, with a low rate of Grade 3 or higher events observed. 23% of patients experienced dose reductions of either medication, and only two patients discontinued treatment due to adverse events. Across Part 1a and Part 1b, there were only two patients with serious adverse events reported that were possibly associated with either study medication including one patient with Grade 2 neutrophil count decrease and pyrexia and Grade 3 platelet count decrease and one patient with Grade 2 bacterial peritonitis and Grade 3 febrile neutropenia. Overall, the safety and tolerability profile of the combination appears consistent with that of single-agent sunitinib, suggesting that bezuclastinib is not adding to the overall frequency or severity of adverse events associated with single-agent sunitinib.

Clinical Activity Data

As of the cutoff date, 39 patients had been treated for at least one 28-day cycle, with a range of 1-13 cycles, and 25 of the 39 patients continue to receive treatment. Data were immature to estimate median progression free survival. Across the efficacy evaluable patients in Part 1, the disease control rate (CR + PR + durable SD) is currently 55%; including a 100% disease control rate and 17% overall response rate among the efficacy evaluable 2nd-line patients in Part 1a. Across the study, 21 patients have demonstrated radiographic evidence of reduction in target lesion diameter, including four patients who have achieved partial response. Among those responders the time to first response was as long as eight cycles, suggesting that patients currently early in treatment may achieve responses over time.

As of June 1, 2023 four of the seven second-line patients in Part 1a remained on study with at least 10 cycles of therapy.

Bezuclastinib Clinical Development

The Company is actively enrolling patients in Part 2 of the Phase 3 registration-enabling PEAK trial, which is expected to include approximately 388 second-line, post-imatinib GIST patients. Additionally, the Company remains on track to present initial clinical data from SUMMIT, a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 trial of bezuclastinib in patients with nonadvanced systemic mastocytosis in the second half of 2023. Data will include safety/tolerability, pharmacokinetics, and measures of clinical activity. The Company also expects to present clinical data from approximately 30 patients in Part 1 of the Phase 2 APEX trial in patients with advanced systemic mastocytosis at a scientific meeting in the second half of 2023.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the potential for bezuclastinib to bring a new standard of care to imatinib-resistant GIST patients, the anticipated size of the Company's Phase 3 PEAK trial, the Company's plan to present initial clinical data from SUMMIT in the second half of 2023, and the Company's plan to present clinical data from Part 1 of the APEX trial at a scientific meeting in the second half of 2023. 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 the Company's current

beliefs, expectations and assumptions regarding the future of the Company's business, future plans and strategies, the Company's clinical results, the rate of enrollment in the Company's 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. The Company may not actually achieve the forecasts or milestones disclosed in its forward-looking statements, and you should not place undue reliance on its 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 the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent filings made with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Neither the Company's, nor its 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 the Company's views as of any date subsequent to the date hereof.

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 6, 2023

COGENT BIOSCIENCES, INC.

By: /s/ Evan Kearns
Evan Kearns
Chief Legal Officer