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): March 14, 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	**02451**
(Address of principal executive offices)	**(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 2.02 Results of Operations and Financial Condition.

On March 14, 2023, Cogent Biosciences, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter and year ended December 31, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference in its entirety.

The information in this Item 2.02 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Cogent Biosciences, Inc. on March 14, 2023, furnished herewith.
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: March 14, 2023

COGENT BIOSCIENCES, INC.

By: /s/ John Green
John Green
Chief Financial Officer

Cogent Biosciences Reports Recent Business Highlights and Fourth Quarter and Full Year 2022 Financial Results

Initiation of APEX Part 2 planned for mid-2023

Updated clinical data from Phase 3 PEAK lead-in in GIST patients expected 1H23

Initial clinical data from Phase 2 SUMMIT trial in NonAdvSM on-track for 2H23

Ended 2022 with $259.3 million in cash; sufficient to fund operations into 2025

WALTHAM, Mass. and BOULDER, Colo., March 14, 2023 - Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today provided a business update and reported financial results for the fourth quarter and full year of 2022.

"2022 was a pivotal year for Cogent marked by our promising clinical data with bezuclastinib in systemic mastocytosis, the initiation of our Phase 3 PEAK trial in GIST, and the build-out of the Cogent Research Team," said Andrew Robbins, the company's President and Chief Executive Officer. "We have laid the foundation for multiple catalysts in 2023 across all our programs. Based on the clinical performance of bezuclastinib, we believe it has the potential to be a best-in-class therapy for patients living with systemic mastocytosis and GIST. We continue to advance therapies that improve the lives of patients with genetically defined rare diseases while positioning ourselves as an industry leader in precision medicine."

Recent Highlights

- In March 2023, Cogent received approvals from European regulatory authorities to initiate the Phase 2 SUMMIT trial in patients with nonadvanced systemic mastocytosis (NonAdvSM). Beginning in April 2023, the company expects to start activating clinical trial sites across major countries in the European Union.
- In December 2022, Cogent reported positive updated clinical data from the ongoing Phase 2 APEX trial evaluating bezuclastinib in patients with advanced systemic mastocytosis (AdvSM) at the American Society of Hematology (ASH) annual meeting.
    - As of the cutoff date, October 26, 2022, 11 patients were evaluable for response per the modified IWG-MRT-ECNM criteria. 89% ORR (including centrally adjudicated confirmed and unconfirmed responses) was seen in TKI therapy naïve patients, including 67% of patients achieving CR, CRh or PR, and 22% of patients achieving CR or CRh. Additionally, bezuclastinib demonstrated rapid reductions in serum tryptase, with an 85% mean reduction

in serum tryptase, 14/16 patients achieving ≥ 50% reduction in serum tryptase levels, and eight of these patients achieving serum tryptase of <20ng/mL. Bezuclastinib was generally well-tolerated at all doses. There were no related cases of cognitive impairment and no reported bleeding events, which have been associated with other KIT inhibitors.

- In November 2022, Cogent reported positive clinical lead-in data from the ongoing Phase 3 PEAK trial evaluating bezuclastinib in combination with sunitinib in patients with Gastrointestinal Stromal Tumors (GIST) at the Connective Tissue Oncology Society (CTOS) annual meeting.
    - As of the cutoff date, September 26, 2022, 17 of 19 patients remained on study. Early data suggested an encouraging safety and tolerability profile consistent with the previous Phase 1/2 study and the known safety profile for sunitinib monotherapy.
- In October 2022, Cogent reported preclinical data at the EORTC-NCI-AACR (ENA) annual meeting on a next-generation fibroblast growth factor receptor 2 (FGFR2) program, which retains potency across all primary, gatekeeper and molecular brake resistance mutations, including N549K and V564I, while sparing FGFR1 inhibition. Also, Cogent presented preclinical data at ENA on a novel ErbB2 mutant selective program which demonstrates robust cellular inhibition of all key resistance and primary driver mutations, including L755S, V842I and S310F/Y, while sparing wild type EGFR target engagement.
- Appointed Rachael Easton, MD, Ph.D., Vice President, Head of Clinical Development. Prior to joining Cogent, Dr. Easton was Group Senior Medical Director, Oncology Clinical Development at GSK. Prior to GSK, she held clinical development roles of increasing responsibility at Immunocore and Sanofi. Before transitioning into the biotechnology industry, Dr. Easton was an instructor at the University of Pennsylvania School of Medicine where she conducted research in growth and metabolism and provided outpatient care for patients with endocrine disorders.
- Appointed Sylvia Adams, MD to Cogent's Scientific Advisory Board. Dr. Adams is a Professor of Medicine at the NYU Grossman School of Medicine and Director of the Breast Cancer Center at the Laura and Isaac Perlmutter Cancer Center. As an internationally recognized expert in breast cancer immunotherapy, she has led groundbreaking research and clinical studies leading to the first chemo-immunotherapy approval for breast cancer. She is a member of the ECOG-ACRIN Breast Cancer Committee and at present, co-chairs the NCI Breast Cancer Immuno-Oncology Task Force.

Upcoming Milestones

- Present updated clinical data from refractory GIST patients in the lead-in cohort of the Phase 3 PEAK trial of bezuclastinib plus sunitinib during the first half of 2023.
- Provide a mid-year update on the planned initiation of APEX Part 2 based on clinical data from approximately 25-30 patients in APEX Part 1.
- Present initial clinical data from SUMMIT, a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 clinical trial of bezuclastinib in patients with NonAdvSM in the second half of 2023. Clinical data is expected to include safety/tolerability, pharmacokinetics and measures of clinical activity.
- Present updated preclinical data from Cogent's selective FGFR2 and ErbB2 research programs at the American Association for Cancer Research annual meeting taking place April 14-19, 2023 in Orlando, Florida.

Fourth Quarter and Full Year 2022 Financial Results

Cash and Cash Equivalents: As of December 31, 2022, Cogent had cash, cash equivalents and marketable securities of $259.3 million. The company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into 2025. Cogent holds a de minimis amount of cash related balances at Silicon Valley Bank.

R&D Expenses: Research and development expenses were $36.7 million for the fourth quarter of 2022 and $121.6 million for the year ended December 31, 2022, as compared to $20.5 million for the fourth quarter of 2021 and $55.9 million for the year ended December 31, 2021. The increase is primarily a result of bezuclastinib clinical trial activities. R&D expenses include non-cash stock compensation expense of $2.4 million for the fourth quarter of 2022 and $8.5 million for the year ended December 31, 2022, as compared to $1.7 million for the fourth quarter of 2021 and $4.4 million for the year ended December 31, 2021.

G&A Expenses: General and administrative expenses were $7.0 million for the fourth quarter of 2022 and $26.2 million for the year ended December 31, 2022, as compared to $5.1 million for the fourth quarter of 2021 and $19.6 million for the year ended December 31, 2021. G&A expenses include non-cash stock compensation expense of $2.6 million for the fourth quarter of 2022 and $9.9 million for the year ended December 31, 2022, as compared to $2.1 million for the fourth quarter of 2021 and $7.3 million for the year ended December 31, 2021.

Net Loss: Net loss was $39.6 million for the fourth quarter of 2022 and $140.2 million for the year ended December 31, 2022, as compared to a net loss of $24.9 million for the fourth quarter of 2021 and $72.3 million for the year ended December 31, 2021.

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 FGFR2 and ErbB2. 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: Twitter and LinkedIn. Information that may be important to investors will be routinely posted on our website and Twitter.

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 company's cash runway, the potential for bezuclastinib to become a best-in-class treatment option for patients living with systemic mastocytosis and GIST, plans to provide a mid-year update on the planned initiation of APEX Part 2 based on clinical data from approximately 25-30 patients in APEX Part 1, plans to present updated clinical data from the Phase 3 PEAK lead-in study during the first half of 2023, plans to start activating clinical trial sites across major countries in the European Union for SUMMIT in April 2023 and to present initial clinical data from SUMMIT in the second half of 2023, and plans to present updated preclinical data from the company's research programs in April 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 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.

COGENT BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 36,742	$ 20,514	$ 121,627	$ 55,913
General and administrative	7,003	5,125	26,212	19,638
Total operating expenses	43,745	25,639	147,839	75,551
Loss from operations	(43,745)	(25,639)	(147,839)	(75,551)
Other income:				
Interest income	2,110	106	3,989	467
Other income, net	657	621	2,249	2,468
Change in fair value of CVR liability	1,360	—	1,360	343
Total other income, net	4,127	727	7,598	3,278
Net loss	$ (39,618)	$ (24,912)	$ (140,241)	$ (72,273)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.56)	$ (0.60)	$ (2.39)	$ (1.87)
Weighted average common shares outstanding, basic and diluted	70,489,607	41,666,415	58,739,713	38,730,813

COGENT BIOSCIENCES, INC.
SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)
(unaudited)

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 259,276	$ 219,684
Working capital	$ 238,117	$ 205,556
Total assets	$ 300,810	$ 232,092
Total liabilities	$ 45,075	$ 17,908
Total stockholders' equity	$ 255,735	$ 214,184

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