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): May 10, 2022

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.)**

200 Cambridge Park Drive, Suite 2500
Cambridge, Massachusetts **02140**
(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 May 10, 2022, Cogent Biosciences, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 May 10, 2022, 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: May 10, 2022

COGENT BIOSCIENCES, INC.

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

Cogent Biosciences Reports Recent Business Highlights and First Quarter 2022 Financial Results

Initial bezuclastinib APEX data to be presented at the European Hematology Association (EHA) 2022 Annual Congress

Building a portfolio of discovery stage programs, creating potential best-in-class small molecule kinase inhibitors for genetically defined oncology indications and rare diseases

Ended 1Q 2022 with $191.0 million in cash, sufficient to fund operations into 2024

CAMBRIDGE, Mass. and BOULDER, Colo., May 10, 2022 – Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced financial results for the first quarter ended March 31, 2022.

"We continue to make significant progress towards our strategic priorities for 2022," said Andrew Robbins, President and CEO of Cogent Biosciences. "We look forward to presenting initial clinical data from our APEX trial of bezuclastinib in advanced systemic mastocytosis patients at the annual EHA meeting this June. This presentation will include patient data from each dose cohort of bezuclastinib, including levels of serum tryptase, a validated biomarker of mast cell activity. We also continue to enroll patients in the SUMMIT and PEAK trials with bezuclastinib. In addition, our research team has rapidly advanced our pipeline with the addition of our FGFR2 and ErbB2 programs, each with clear differentiation from other programs in development and best-in-class potential. With these important advances, we believe we are well positioned to build on our momentum to bring important therapies to patients with genetically defined diseases."

Upcoming Milestones and Recent Business Highlights

- On track to report initial clinical data from APEX, a global, multicenter, Phase 2 clinical trial of bezuclastinib, a potent, highly selective, minimally brain-penetrant KIT mutant inhibitor in patients with Advanced Systemic Mastocytosis (AdvSM) in the second quarter of 2022.
    - Data to be presented at the European Hematology Association (EHA) 2022 Annual Congress will include safety and tolerability from patients across each dose cohort, as well as levels of serum tryptase, a validated biomarker of mast cell activity. The hybrid conference will take place in Vienna, Austria from June 9-12, 2022.

- Presented early data and outlined Cogent's strategy to create best-in-class small molecules from the company's growing pipeline of novel, targeted therapy programs at the American Association of Cancer Research (AACR) annual meeting and Cogent R&D investor event.
    - Advancing a potent, selective FGFR2 inhibitor toward candidate selection with a product profile that includes best-in-class selectivity and potency against all known FGFR2 primary driver and secondary resistance mutations. On track for first internally developed Investigational New Drug application (IND) in the second half of 2023.
    - Announced development of an ErbB2 mutant selective inhibitor for patients with mutations that are not well addressed by therapies currently approved or in clinical development.

- Shared additional nonclinical data demonstrating bezuclastinib's potential as a best-in-class KIT mutant inhibitor during the 2022 AACR annual meeting.
    - Presentations demonstrated bezuclastinib has a unique profile as a potent, mutant KIT inhibitor (including KIT D816V) with minimal brain penetration and no activity against related kinases including PDGFR, FLT3 and CSF1R, which have been linked to off-target toxicities including edema and pleural effusions.

- Actively enrolling patients in SUMMIT, a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 clinical trial with bezuclastinib for nonadvanced systemic mastocytosis (NonAdvSM).
    - SUMMIT is designed to evaluate the safety and efficacy of bezuclastinib in patients with moderate to severe Indolent Systemic Mastocytosis (ISM) or Smoldering Systemic Mastocytosis (SSM).

- Actively enrolling patients in PEAK, a registrational randomized, open-label, global, Phase 3 clinical trial in patients with Gastrointestinal Stromal Tumors (GIST)**.**
    - PEAK is designed to evaluate the efficacy and safety of bezuclastinib in combination with sunitinib compared to sunitinib alone in patients with locally advanced, unresectable or metastatic GIST who have received prior treatment with imatinib.

First Quarter 2022 Financial Results

- **Cash and Cash Equivalents:** As of March 31, 2022, cash and cash equivalents were $191.0 million as compared to $219.7 million as of December 31, 2021. Based on its current plans, the company expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into 2024.

- **R&D Expenses:** Research and development expenses were $25.5 million for the first quarter of 2022 compared to $8.2 million for the first quarter of 2021. The increase was primarily due to costs associated with the on-going APEX, SUMMIT and PEAK clinical trials and costs related to expanding the Cogent Research Team, which was formed in the second quarter of 2021.

- **G&A Expenses**: General and administrative expenses were $5.9 million for the first quarter of 2022 compared to $4.6 million for the first quarter of 2021. The increase was primarily due to the growth of the organization.

- **Net Loss:** Net loss was $30.6 million for the first quarter of 2022 compared to a net loss of $11.7 million for the first quarter of 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 Cambridge, 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 anticipated cash runway, the presentation of initial clinical data from APEX at EHA in June 2022, the best-in-class potential of the company's research programs, including its FGFR2 and ErbB2 programs, and clinical development and regulatory plans and timelines, including the plan to file an IND in the second half of 2023 for the company's FGFR2 inhibitor candidate. 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 Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	25,470	8,213
General and administrative	5,948	4,587
Total operating expenses	31,418	12,800
Loss from operations	(31,418)	(12,800)
Other income:		
Interest income	107	125
Other income	677	604
Change in fair value of CVR liability	—	343
Total other income	784	1,072
Net loss	$ (30,634)	$ (11,728)

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 191,047	$ 219,684
Working Capital	$ 176,854	$ 205,556
Total assets	$ 206,869	$ 232,092
Total liabilities	$ 19,006	$ 17,908
Total stockholders' equity	$ 187,863	$ 214,184

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