# 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 9, 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 May 9, 2023, Cogent Biosciences, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 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 May 9, 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: May 9, 2023

**COGENT BIOSCIENCES, INC.**

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

# Cogent Biosciences Reports Recent Business Highlights and First Quarter 2023 Financial Results

*Lead-in data from Phase 3 PEAK trial to be presented at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting*

*Announced initiation of APEX Part 2 expansion trial; on-track to present initial SUMMIT clinical data in 2H 2023*

*Ended 1Q 2023 with $220.3 million in cash, sufficient to fund operations into 2025*

**WALTHAM, Mass. and BOULDER, Colo., May 9, 2023** – Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today provided a business update and announced financial results for the first quarter ended March 31, 2023.

"Cogent continued to make important progress in the first quarter," said Andrew Robbins, the Company's President and Chief Executive Officer. "With three active clinical programs, 2023 will be a year rich in data and milestones that build upon our scientific achievements. We look forward to sharing lead-in data of bezuclastinib plus sunitinib from our PEAK trial in GIST patients at ASCO. We are pleased with the progress in our SUMMIT trial in NonAdvSM patients and remain on track to report initial clinical data in the second half of 2023. Additionally, we are planning a robust clinical update from approximately 30 patients with AdvSM from our APEX Part 1 study, also in the second half of the year. With these catalysts, a preclinical pipeline with best-in-class potential and a cash runway into 2025, we believe we are well positioned to build on our momentum to bring important therapies to patients fighting rare, genetically driven diseases."

**Recent Business Highlights**

- Initiated Part 2 of the ongoing Phase 2 APEX trial evaluating bezuclastinib in Advanced Systemic Mastocytosis (AdvSM) following completion of enrollment in Part 1.
    - Part 2 will enroll approximately 65 patients treated at a once-daily 150 mg optimized dose and if successful, is designed to support regulatory submission. Enrollment is expected to be complete by the end of 2024.

- Presented preclinical data from the company's ErbB2 and FGFR2 research programs at the American Association of Cancer Research (AACR) annual meeting.
    - Preclinical data described a novel EGFR-sparing, brain-penetrant ErbB2 inhibitor with potency across key oncogenic ErbB2 mutations.
    - In vivo characterization showed a novel, selective, reversible FGFR2 inhibitor that has potency against molecular brake and gatekeeper mutations, with potential advantages over covalent approaches.

- Received approvals from European regulatory authorities to initiate the Phase 2 SUMMIT trial in patients with nonadvanced systemic mastocytosis (NonAdvSM) and rapidly activating clinical trial sites across major countries in the European Union.

- FDA granted Orphan Drug Designation for bezuclastinib for the treatment of mastocytosis, including systemic mastocytosis (SM) with an estimated 30,000 SM cases diagnosed annually in the United States.

**Upcoming Milestones**

- Present a poster highlighting updated safety and tolerability data from Part 1 of PEAK, the Company's ongoing Phase 3 trial evaluating bezuclastinib in combination with sunitinib in patients with Gastrointestinal Stromal Tumors (GIST), at the 2023 ASCO Annual Meeting taking place June 2-6, 2023, in Chicago, IL.
    - **Title:** Safety, Pharmacokinetics (PK), and Clinical Activity of Bezuclastinib + Sunitinib in Previously-Treated Gastrointestinal Stromal Tumor (GIST): Results from Part 1 of the Phase 3 Peak Study
        - **Presenter:** Dr. William Tap
        - **Abstract number:** 11537
        - **Date and time:** 6/3/2023, 1:15-4:15pm CT
        - **Session:** Sarcoma

    - Data will include measures of safety and tolerability, along with clinical activity, including duration of therapy and objective response rate. Cogent will host an investor webcast to discuss these results. Details will be provided closer to the event.

- 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. Data will include safety/tolerability, pharmacokinetics and measures of clinical activity.

- Present clinical data from approximately 30 patients in Part 1 of APEX in patients with AdvSM at a scientific meeting in the second half of 2023.

**First Quarter 2023 Financial Results**

**Cash and Cash Equivalents:** As of March 31, 2023, cash, cash equivalents and marketable securities were $220.3 million as compared to $259.3 million as of December 31, 2022. Total cash spent was $39.0 million, including a one-time payment of $5.1 million related to performance-based bonus compensation. Based on its current plans, the company expects its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into 2025.

**R&D Expenses:** Research and development expenses were $36.0 million for the first quarter of 2023 compared to $25.5 million for the first quarter of 2022. The increase was primarily due to costs associated with the on-going APEX, SUMMIT and PEAK clinical trials and costs related to development of the research pipeline. R&D expenses include non-cash stock compensation expense of $3.0 million for the first quarter of 2023 as compared to $1.9 million for the first quarter of 2022.

**G&A Expenses**: General and administrative expenses were $7.2 million for the first quarter of 2023 compared to $5.9 million for the first quarter of 2022. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $2.9 million for the first quarter of 2023 as compared to $2.3 million for the first quarter of 2022.

**Net Loss:** Net loss was $38.6 million for the first quarter of 2023 compared to a net loss of $30.6 million for the first quarter of 2022.

**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 clinical development plans and timelines, including the expectation to complete enrollment for Part 2 of the Company's APEX trial by the end of 2024, the Company's projected cash runway, potential advantages of the Company's preclinical ErbB2 and FGFR programs, the expectation for 2023 to be a year rich in data and milestones, including the Company's plans to present clinical data from its Phase 3 PEAK lead-in study in GIST patients at ASCO in June 2023, the Company's plans to present clinical data from its SUMMIT trial in NonAdvSM patients in the second half of 2023, and the Company's plans to present updated clinical data from Part 1 of its APEX trial in AdvSM patients 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 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**
*(in thousands, except share and per share amounts)*
*(unaudited)*

| | Three Months Ended March 31, | |
|---|---|---|
| | 2023 | 2022 |
| Operating expenses: | | |
| Research and development | $ 36,038 | $ 25,470 |
| General and administrative | 7,199 | 5,948 |
| Total operating expenses | 43,237 | 31,418 |
| Loss from operations | (43,237) | (31,418) |
| Other income: | | |
| Interest income | 2,268 | 107 |
| Other income, net | 682 | 677 |
| Change in fair value of CVR liability | 1,700 | — |
| Total other income, net | 4,650 | 784 |
| Net loss | $ (38,587) | $ (30,634) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.54) | $ (0.68) |
| Weighted average common shares outstanding, basic and diluted | 70,734,950 | 45,105,923 |

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

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 220,264 | $ 259,276 |
| Working capital | $ 205,150 | $ 238,117 |
| Total assets | $ 263,198 | $ 300,810 |
| Total liabilities | $ 39,635 | $ 45,075 |
| Total stockholders' equity | $ 223,563 | $ 255,735 |

**Contact:**
Christi Waarich
Senior Director, Investor Relations
christi.waarich@cogentbio.com
617-830-1653