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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): February 26, 2024

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**COGENT BIOSCIENCES, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38443**  
(Commission  
File Number)

**46-5308248**  
(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)

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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           |

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On February 26, 2024, 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        | <a href="#">Press release issued by Cogent Biosciences, Inc. on February 26, 2024, furnished herewith.</a> |
| 104         | The cover page from the Company’s Current Report on Form 8-K formatted in Inline XBRL.                     |

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**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: February 26, 2024

**COGENT BIOSCIENCES, INC.**

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

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## **Cogent Biosciences Reports Recent Business Highlights and Fourth Quarter and Full Year 2023 Financial Results**

*SUMMIT Part 2 registration-directed study of bezuclastinib in NonAdvSM patients initiated and actively enrolling at 40 sites globally; once-daily 100 mg selected as RP2D; topline results expected by YE 2025*

*PEAK Phase 3 study of bezuclastinib + sunitinib in 2nd-line GIST patients on track to complete enrollment by end of 2024; topline results expected by YE 2025*

*APEX Part 2 registration-directed study of bezuclastinib in AdvSM patients on track to complete enrollment by end of 2024; topline results expected by mid-2025*

*\$487 million in pro-forma cash sufficient to fund operations into 2027; includes net proceeds from oversubscribed \$225 million February 2024 PIPE*

**WALTHAM, Mass. and BOULDER, Colo., February 26, 2024** -- 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 2023.

“We have entered 2024 in a very strong position,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “We are now actively enrolling three registration-directed clinical trials of bezuclastinib across NonAdvSM, AdvSM and 2nd-line GIST patients, all of which are on track to deliver top-line results in 2025. With our recent fundraising, we are funded into 2027, and based on the clinical data we have presented across these programs to date, believe strongly that bezuclastinib has the opportunity to become the best-in-class KIT mutant inhibitor for these three indications.”

### **Q4 2023 and Recent Business Highlights**

- In February 2024, reported positive Part 1b data from the Company’s ongoing Phase 2 SUMMIT trial at the 2024 American Academy of Allergy Asthma & Immunology Annual Meeting (AAAAI) meeting. SUMMIT is a registration-directed, randomized, double-blind, placebo-controlled, global, multicenter, clinical trial of bezuclastinib in patients with nonadvanced systemic mastocytosis (NonAdvSM). Key highlights include:
  - o Announced the 100 mg Recommended Phase 2 Dose (RP2D)
  - o Demonstrated a well-tolerated safety profile, generally consistent with placebo
  - o Introduced Cogent’s MS2D2, a novel, refined patient reported outcomes measure (PROM) designed to assess symptomatic severity and improvement
  - o Reported a 51% week 12 mean improvement in total symptom score (TSS) for bezuclastinib, including 70% of patients achieving  $\geq 50\%$  improvement in symptom severity
  - o Reported a 49% week 12 mean improvement in quality of life (MC-QoL) for bezuclastinib

- In February 2024, closed a \$225 million oversubscribed private investment in public equity (PIPE) financing. Cogent sold approximately 17 million shares of its common stock at a price of \$7.50 per share, representing a premium of approximately 37% to its closing price on February 13, 2024. The financing also included Series B non-voting convertible Preferred Stock convertible into approximately 13 million shares of its common stock.
  - In December 2023, reported positive clinical data from the Phase 2 SUMMIT and APEX trials at the American Society of Hematology (ASH) annual meeting. Highlights from APEX, a registration-directed trial evaluating bezuclastinib in patients with advanced systemic mastocytosis (AdvSM), include:
    - o Reported an encouraging safety and tolerability profile with no related cognitive impairment or bleeding events
    - o Achieved impressive effects in key biomarkers of disease burden
    - o Achieved 56% Overall Response Rate (ORR) in TKI-naïve patients, including 86% ORR by Pure Pathological Response (PPR) criteria
  - In December 2023, presented new preclinical data highlighting the potential best-in-class potency and selectivity of Cogent's ErbB2 inhibitor and announced a third Cogent discovery stage PI3K $\alpha$  inhibitor program at the San Antonio Breast Cancer Symposium (SABCS).
    - o The novel EGFR-sparing, brain-penetrant ErbB2 inhibitor demonstrated a superior efficacy profile, reaching 80% brain penetrance with potent coverage of key mutations
    - o The novel, H1047R mutant-selective PI3K $\alpha$  inhibitor demonstrated high clinical target engagement without metabolic dysfunction commonly associated with molecules in the class
  - In November 2023, reported updated clinical data from the lead-in portion of the ongoing PEAK Phase 3 trial evaluating bezuclastinib in combination with sunitinib in patients with GIST at the Connective Tissue Oncology Society (CTOS) annual meeting. Positive lead-in data was first presented at the 2023 American Society of Clinical Oncology (ASCO) annual meeting in June.
    - o Safety and tolerability data from 42 patients enrolled in Part 1a and Part 1b were consistent with results shared at the 2023 ASCO annual meeting, demonstrating the combination of bezuclastinib and sunitinib was well tolerated with an adverse event profile similar to sunitinib monotherapy
    - o Updated clinical activity from a subset of 2nd-line GIST patients demonstrated a 33% confirmed overall response rate (ORR) with ongoing median duration of therapy greater than 14 months. Together with clinical data previously reported from a Phase 1/2 trial, 4 of 10 evaluable 2nd-line GIST patients treated with the combination have reached confirmed partial response status
  - In October 2023, presented updated preclinical data from the Company's next-generation selective fibroblast growth factor receptor 2 (FGFR2) program in a poster presentation at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.
    - o The poster showed Cogent's internally-developed FGFR2 inhibitor exhibits low nM potency on WT FGFR2 and FGFR2 mutations and is selective against the kinome and a panel of channels and receptors.
    - o Exploratory pharmacokinetics (PK) studies conducted across species showed CGT4859 to be a low-clearance compound with high oral bioavailability. Further, in an AN3 CA model, CGT4859 demonstrated dose-responsive tumor growth inhibition with complete regressions at 5 mg/kg PO and was well-tolerated
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## **Projected Near-Term Milestones**

### ***Bezuclastinib – Systemic Mastocytosis (SM)***

- Complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and deliver top-line results by the end of 2025
- Provide additional safety, tolerability and patient-reported outcomes data from the open label extension portion of SUMMIT Part 1 during 2024
- Complete enrollment in the registration-directed APEX Phase 2 trial in patients with Advanced Systemic Mastocytosis (AdvSM) by the end of 2024

### ***Bezuclastinib – Gastrointestinal Stromal Tumors (GIST)***

- Complete enrollment in the global, randomized Phase 3 PEAK trial in 2nd-line GIST patients by the end of 2024
- Provide additional clinical results from the PEAK lead-in trial, including longer duration safety and tolerability results along with updated efficacy measures, including objective response rate (ORR) and progression free survival (PFS) during 2024

### ***CGT4859 (FGFR2 inhibitor)***

- Initiate a Phase 1 trial of the first Cogent-discovered pipeline program, designed as a potent, selective, reversible FGFR2 inhibitor with best-in-class potential in the second half of 2024

### ***Preclinical Pipeline***

- Initiate IND-enabling studies for lead candidate from potent, selective ErbB2 program, highlighted by potential best-in-class brain penetrant properties
  - Select lead candidate and initiate IND-enabling studies from ongoing PI3K program, designed to potently and selectively target the H1047R driver mutation, which affects >30,000 cancer patients each year
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## **Upcoming Investor Conference**

- Leerink Healthcare Conference on Tuesday, March 12 at 2:20 p.m. ET.
  - o A live webcast can be accessed on the Investors & Media page of Cogent's website at [investors.cogentbio.com/events](https://investors.cogentbio.com/events). A replay will be available approximately two hours after completion of the events and will be archived for up to 30 days.

## **Fourth Quarter and Full Year 2023 Financial Results**

**Cash and Cash Equivalents:** As of December 31, 2023, Cogent had cash, cash equivalents and marketable securities of \$273.2 million. Cogent believes this year-end balance, together with the gross proceeds from the \$225.0 million oversubscribed private placement, which closed February 16, 2024, will be sufficient to fund its operating expenses and capital expenditure requirements into 2027, including through clinical readouts from the ongoing SUMMIT, PEAK and APEX registration-directed trials.

**R&D Expenses:** Research and development expenses were \$48.7 million for the fourth quarter of 2023 and \$173.8 million for the year ended December 31, 2023, as compared to \$36.7 million for the fourth quarter of 2022 and \$121.6 million for the year ended December 31, 2022. The increase is driven by progress on the APEX, SUMMIT and PEAK trials and the continued development of the research pipeline. During the quarter Cogent also completed and paid for bulk manufacturing campaigns of bezuclastinib to continue supporting the company's clinical trials. R&D expenses include non-cash stock compensation expense of \$4.1 million for the fourth quarter of 2023 and \$14.6 million for the year ended December 31, 2023, as compared to \$2.4 million for the fourth quarter of 2022 and \$8.5 million for the year ended December 31, 2022.

**G&A Expenses:** General and administrative expenses were \$9.5 million for the fourth quarter of 2023 and \$34.4 million for the year ended December 31, 2023, as compared to \$7.0 million for the fourth quarter of 2022 and \$26.2 million for the year ended December 31, 2022. G&A expenses include non-cash stock compensation expense of \$4.8 million for the fourth quarter of 2023 and \$16.0 million for the year ended December 31, 2023, as compared to \$2.6 million for the fourth quarter of 2022 and \$9.9 million for the year ended December 31, 2022.

**Net Loss:** Net loss was \$54.4 million for the fourth quarter of 2023 and \$192.4 million for the year ended December 31, 2023, as compared to a net loss of \$39.6 million for the fourth quarter of 2022 and \$140.2 million for the year ended December 31, 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 mutations in FGFR2, ErbB2 and PI3K $\alpha$ . Cogent Biosciences is based in Waltham, MA and Boulder, CO. Visit our website for more information at [www.cogentbio.com](https://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](#).

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## 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 for SUMMIT to complete enrollment in the second quarter of 2025 and deliver top-line results by the end of 2025; the expectation for PEAK to complete enrollment by the end of 2024 and to deliver top-line results by the end of 2025; the expectation for APEX to complete enrollment by the end of 2024 and to deliver top-line results by mid-2025; the company's anticipated cash runway into 2027; the expectation that bezuclastinib has the opportunity to become the best-in-class KIT mutant inhibitor for NonAdvSM, AdvSM and 2<sup>nd</sup>-line GIST patients; the potential best-in-class potency and selectivity of the company's ErbB2 inhibitor; plans to provide additional safety, tolerability and patient-reported outcomes data from the open label extension portion of SUMMIT Part 1 during 2024; plans to provide additional clinical results from the PEAK lead-in trial, including longer duration safety and tolerability results along with updated efficacy measures, including ORR and PFS, during 2024; plans to initiate a Phase 1 trial of the first internally-discovered pipeline program, designed as a potent, selective, reversible FGFR2 inhibitor with best-in-class potential, in the second half of 2024; plans to initiate IND-enabling studies for lead candidate from potent, selective ErbB2 program, highlighted by potential best-in-class brain penetrant properties; and plans to select a lead candidate and initiate IND-enabling studies from ongoing PI3Ka program. 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 or 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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**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, |              |
|---|---------------------------------|-------------|-------------------------|--------------|
|   | 2023                            | 2022        | 2023                    | 2022         |
| Operating expenses:   |                                 |             |                         |              |
| Research and development  | \$ 48,719                       | \$ 36,742   | \$ 173,755              | \$ 121,627   |
| General and administrative  | 9,509                           | 7,003       | 34,375                  | 26,212       |
| Total operating expenses  | 58,228                          | 43,745      | 208,130                 | 147,839      |
| Loss from operations  | (58,228)                        | (43,745)    | (208,130)               | (147,839)    |
| Other income:   |                                 |             |                         |              |
| Interest income   | 3,870                           | 2,110       | 13,077                  | 3,989        |
| Other income, net   | (7)                             | 657         | 943                     | 2,249        |
| Change in fair value of CVR liability                                     | --                              | 1,360       | 1,700                   | 1,360        |
| Total other income, net   | 3,863                           | 4,127       | 15,720                  | 7,598        |
| Net loss  | \$ (54,365)                     | \$ (39,618) | \$ (192,410)            | \$ (140,241) |
| Net loss per share attributable to common stockholders, basic and diluted | \$ (0.63)                       | \$ (0.56)   | \$ (2.42)               | \$ (2.39)    |
| Weighted average common shares outstanding, basic and diluted             | 86,730,309                      | 70,489,607  | 79,657,942              | 58,739,713   |

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

|  | December 31, | December 31, |
|--|--------------|--------------|
|  | 2023         | 2022         |
| Cash, cash equivalents and marketable securities | \$ 273,170   | \$ 259,276   |
| Working capital                                  | \$ 232,603   | \$ 238,117   |
| Total assets                                     | \$ 313,437   | \$ 300,810   |
| Total liabilities                                | \$ 55,635    | \$ 45,075    |
| Total stockholders' equity                       | \$ 257,802   | \$ 255,735   |

**Contact:**  
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