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

February 26, 2024

- *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., Feb. 26, 2024 (GLOBE NEWSWIRE) -- 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:
  - Announced the 100 mg Recommended Phase 2 Dose (RP2D)
  - Demonstrated a well-tolerated safety profile, generally consistent with placebo
  - Introduced Cogent's MS2D2, a novel, refined patient reported outcomes measure (PROM) designed to assess symptomatic severity and improvement
  - Reported a 51% week 12 mean improvement in total symptom score (TSS) for bezuclastinib, including 70% of patients achieving ≥50% improvement in symptom severity
  - 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:
  - Reported an encouraging safety and tolerability profile with no related cognitive impairment or bleeding events
  - Achieved impressive effects in key biomarkers of disease burden
  - 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 PI3Kα inhibitor program at the San Antonio Breast Cancer Symposium (SABCS).

- The novel EGFR-sparing, brain-penetrant ErbB2 inhibitor demonstrated a superior efficacy profile, reaching 80% brain penetrance with potent coverage of key mutations
- The novel, H1047R mutant-selective PI3Kα 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.

    - 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
    - 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.

    - 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.
    - 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

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 PI3Ka program, designed to potently and selectively target the H1047R driver mutation, which affects >30,000 cancer patients each year

Upcoming Investor Conference

- Leerink Healthcare Conference on Tuesday, March 12 at 2:20 p.m. ET.

- A live webcast can be accessed on the Investors & Media page of Cogent's website at investors.cogentbio.com/events. A replay will be available approximately two hours after completion of the event 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 PI3Kα. 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: **X** (formerly known as Twitter) and **LinkedIn**. Information that may be important to investors will be routinely posted on our website and **X**.

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 2nd-line GIST patients; the potential best-in-class potency and selectivity of the company's ErbB2 inhibitor; plans to provide addition 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.

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, 2023	December 31, 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

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