Cogent Biosciences Reports Recent Business Highlights and Fourth Quarter and Full Year 2024 Financial Results

February 25, 2025

• Top-line results from SUMMIT trial in NonAdvSM patients expected July 2025

• APEX trial enrollment in AdvSM patients complete; top-line results expected in 2H 2025

• Top-line results from PEAK trial in 2nd-line GIST patients expected by end of 2025

• $312 million sufficient to fund operations well past clinical readouts, into late 2026; includes gross proceeds from ATM sale in February 2025

WALTHAM, Mass. and BOULDER, Colo., Feb. 25, 2025 (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 2024.

“Cogent is preparing to report data from three bezuclastinib pivotal clinical trials this year,” said Andrew Robbins, the company’s President and Chief Executive Officer. “Given our strong cash balance, and emerging pipeline of potential best-in-class targeted therapies, we are poised for a transformational year culminating with the planned submission of Cogent’s first NDA for bezuclastinib by the end of 2025.”

Q4 2024 and Recent Business Highlights

- In December 2024, announced updated clinical results from SUMMIT, showcasing dramatic symptomatic improvement in nonadvanced systemic mastocytosis (NonAdvSM) patients and positive updated data from the APEX trial evaluating bezuclastinib in patients with advanced systemic mastocytosis (AdvSM) at the American Society of Hematology (ASH) annual meeting. In both trials, bezuclastinib continued to demonstrate an encouraging safety and tolerability profile. Highlights include:
    - In SUMMIT, a registration-directed, global, randomized, placebo-controlled trial in patients with NonAdvSM, treatment with 100 mg bezuclastinib demonstrated:
        - 56% mean improvement in Total Symptom Score (TSS) at 24 weeks with 76% of patients achieving at least a >50% reduction from baseline in TSS
        - 89% of patients had >50% decrease in serum tryptase levels by four weeks of treatment
    - In APEX, a registration-directed, global, open-label trial in patients with AdvSM, treatment with various doses of bezuclastinib demonstrated:
        - 52% ORR per mIWG criteria, including 83% ORR for patients receiving 100 mg BID
        - 88% ORR per PPR criteria, including 100% ORR for patients receiving 100 mg BID
        - 2.2 months median time-to-response with median duration-of-response and median PFS not yet reached with at least 20 months follow-up
- In October 2024, announced the addition of a potent and selective KRAS inhibitor to Cogent’s pipeline at the 2024 EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics.
    - Cogent’s internally-developed pan-KRAS(ON) inhibitor demonstrated picomolar (pM) activity across KRAS mutations with selectivity over H/NRAS leading to potential advantages versus other molecules in the class. Following oral administration, CGT6737 demonstrated robust PK/PD and tumor growth inhibition with 90% PD inhibition in mouse xenograft models. Lead optimization of the program is ongoing.
- In October 2024, shared progress on Cogent’s clinical candidate CGT6297, a potent allosteric inhibitor of PI3Kα, with 25-fold selectivity over PI3Kα WT. In a poster at the 2024 EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics, CGT6297 showed high oral bioavailability and low clearance across species, providing robust inhibition of downstream signaling and efficacy in animal models. Importantly, when compared to a clinically relevant dose of a currently approved therapy in a mouse tumor model, CGT6297 demonstrated superior efficacy with no increase in insulin.

Projected Near-Term Milestones

Bezuclastinib – Systemic Mastocytosis (SM)

- Poster presentation focused on symptomatic performance of patients from SUMMIT Part 1 who have received 100 mg bezuclastinib for at least 48 weeks at the 2025 American Academy of Allergy Asthma & Immunology Annual Meeting

(AAAAI).
- Report top-line results in July 2025 from the SUMMIT trial.
- Report top-line results during the second half of 2025 from the APEX trial.
- Submit the first bezuclastinib New Drug Application (NDA) by the end of 2025.

Bezuclastinib – Gastrointestinal Stromal Tumors (GIST)

- Report top-line results by the end of 2025 from the pivotal Phase 3 PEAK trial. PEAK is a global, blinded, randomized clinical trial studying the combination of bezuclastinib and sunitinib versus sunitinib alone in patients with imatinib-resistant gastrointestinal stromal tumors (GIST).

Bezuclastinib - Expanded Access Program

- In Q1, initiate Expanded Access Programs (EAP) in the U.S. for SM and GIST patients to receive investigational bezuclastinib after meeting certain eligibility criteria.

CGT4859 (FGFR2 inhibitor)

- Enroll patients in the ongoing Phase 1 trial with CGT4859, a reversible, selective FGFR2 inhibitor in patients with documented FGFR mutations, including advanced cholangiocarcinoma. The trial is designed to explore the safety, tolerability and clinical activity of escalating doses of CGT4859 with a goal of selecting an active and well-tolerated dose for further clinical investigation.

Preclinical Pipeline

- Submit an IND application in 2025 for CGT4255, a potent, selective ErbB2 inhibitor, highlighted by potential best-in-class brain-penetrant properties.
- Submit an IND application in 2025 for CGT6297, a potent allosteric inhibitor of PI3Kα, with 25-fold selectivity over PI3Kα WT.

Upcoming Investor Conference

- Leerink Healthcare Conference on Wednesday, March 12 at 10:00 a.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 2024 Financial Results

Cash and Cash Equivalents: As of December 31, 2024, Cogent had cash, cash equivalents and marketable securities of $287.1 million. Cogent believes this year-end balance, together with the $25.0 million gross proceeds from shares sold under the Company's at-the-market (ATM) stock offering in February 2025, will be sufficient to fund its operating expenses and capital expenditure requirements into late 2026, including through clinical readouts from the ongoing SUMMIT, PEAK and APEX registration-directed trials.

R&D Expenses: Research and development expenses were $62.0 million for the fourth quarter of 2024 and $232.7 million for the year ended December 31, 2024, as compared to $48.7 million for the fourth quarter of 2023 and $173.8 million for the year ended December 31, 2023. The increase was driven by the development of bezuclastinib, including costs associated with the accelerated completion of enrollment of the SUMMIT and PEAK trials and ongoing cost of the APEX trial, and the continued progression of our research pipeline. R&D expenses include non-cash stock compensation expense of $5.0 million for the fourth quarter of 2024 and $19.0 million for the year ended December 31, 2024, as compared to $4.1 million for the fourth quarter of 2023 and $14.6 million for the year ended December 31, 2023.

G&A Expenses: General and administrative expenses were $11.7 million for the fourth quarter of 2024 and $43.3 million for the year ended December 31, 2024, as compared to $9.5 million for the fourth quarter of 2023 and $34.4 million for the year ended December 31, 2023. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $5.0 million for the fourth quarter of 2024 and $20.8 million for the year ended December 31, 2024, as compared to $4.8 million for the fourth quarter of 2023 and $16.0 million for the year ended December 31, 2023.

Net Loss: Net loss was $67.9 million for the fourth quarter of 2024 and $255.9 million for the year ended December 31, 2024, as compared to a net loss of $54.4 million for the fourth quarter of 2023 and $192.4 million for the year ended December 31, 2023.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)

Cogent also announced today that, on February 12, 2025 and February 24, 2025, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grants of "inducement" equity awards to five new employees under the company's 2020 Inducement Plan with grant dates of February 12, 2025, February 19, 2025 and February 24, 2025. The awards were approved in accordance with Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market. The employees received, in the aggregate, nonqualified options to purchase 78,500 shares of Cogent common stock. Each option has a 10-year term, an exercise price equal to the closing price of Cogent's common stock on the grant date, and a 4-year vesting schedule with 25% vesting on the 1-year anniversary of the grant date and the remainder vesting in equal monthly installments over the subsequent 36 months, provided such employee remains employed through each such vesting date.

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. The company also has an ongoing Phase 1 study of its novel internally discovered FGFR2 inhibitor. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in ErbB2, PI3Kα and KRAS. 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 to report SUMMIT top-line results in July 2025; the expectation to report APEX top-line results in the second half of 2025; the expectation to report PEAK top-line results by the end of 2025; ; the company's anticipated cash runway into late 2026; the planned submission of Cogent's first NDA for bezuclastinib by the end of 2025; the potential best-in-class attributes of the company's pipeline programs; plans to initiate Expanded Access Programs in the first quarter of 2025 in the United States for SM and GIST patients to receive investigational bezuclastinib after meeting certain eligibility criteria; and plans to submit INDs in 2025 for the company's ErbB2 and PI3Kα programs. 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 the date hereof.

COGENT BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 62,045	$ 48,719	$ 232,658	$ 173,755
General and administrative	11,689	9,509	43,281	34,375
Total operating expenses	73,734	58,228	275,939	208,130
Loss from operations	(73,734)	(58,228)	(275,939)	(208,130)
Other income:				
Interest income	3,859	3,870	18,088	13,077
Other income, net	1,948	(7)	1,992	943
Change in fair value of CVR liability	--	--	--	1,700
Total other income, net	5,807	3,863	20,080	15,720
Net loss	$ (67,927)	$ (54,365)	$ (255,859)	$ (192,410)

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

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 287,077	$ 273,170
Working capital	$ 240,762	$ 232,603
Total assets	$ 327,898	$ 313,437
Total liabilities	$ 71,612	$ 55,635
Total stockholders' equity	$ 256,286	$ 257,802

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