Cogent Biosciences Reports Recent Business Highlights and Third Quarter 2024 Financial Results

November 12, 2024

Top-line results from registration-directed SUMMIT, PEAK and APEX trials expected in 2025

Phase 1 trial initiated for CGT-4859, a reversible, potent, selective, FGFR2 inhibitor

SUMMIT and APEX clinical presentations at upcoming ASH annual meeting

Strong cash position of $346 million sufficient to fund operations into late 2026

WALTHAM, Mass. and BOULDER, Colo., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today reported recent business highlights and financial results for the third quarter ended September 30, 2024.

“We made significant progress across our pipeline over the last quarter, including completing enrollment in our Phase 3 PEAK trial in Gastrointestinal Stromal Tumor (GIST) patients, accelerating enrollment in SUMMIT, our registration-directed trial with bezuclastinib in Nonadvanced Systemic Mastocytosis (NonAdvSM) and initiating our first Phase 1 trial with our FGFR2 inhibitor,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “Additionally, we recently presented new preclinical data from our research pipeline that demonstrated potential best-in-class attributes of our pan-KRAS inhibitor and our H1047R PI3Kα inhibitor. As we head into 2025, we are well positioned as we prepare to deliver top-line data from three registrational clinical trials.”

Business Highlights & Milestones

- Completed enrollment in PEAK, a randomized, open-label, global Phase 3 trial evaluating bezuclastinib in combination with sunitinib vs sunitinib alone in patients with imatinib-resistant gastrointestinal stromal tumors (GIST). Based on strong global patient interest, a total of 413 patients were enrolled in the trial. The primary endpoint is median progression free survival (mPFS).
    - In addition, Cogent completed a pre-planned interim futility analysis and the Independent Data Monitoring Committee (IDMC) recommended continuing the PEAK study without modification. This pre-specified analysis was based on an assessment of progression-free survival (PFS) as determined by independent central review and did not include the option for early stopping due to efficacy.

- Cogent will present updated clinical data from both SUMMIT and APEX clinical trials at the upcoming ASH annual meeting in December. There will be an investor webcast on December 9 at 8:00 a.m. ET to review the SUMMIT and APEX data. To register and listen please visit: https://investors.cogentbio.com/events
    - Poster presentation highlighting long term follow-up from patients who participated in the Open Label Extension (OLE) portion of SUMMIT at the ASH annual meeting on Monday, December 9, 2024. SUMMIT is a randomized, global, multicenter, double-blind, placebo-controlled, multi-part Phase 2 trial evaluating bezuclastinib in patients with NonAdvSM.
    - Oral presentation of long term follow-up from patients in Part 1 of the ongoing APEX study to be presented at the 2024 ASH annual meeting on Sunday, December 8, 2024. APEX is a global, multi-part Phase 2 trial evaluating bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM).

- During the quarter, Cogent initiated a Phase 1 study of CGT4859, a reversible, selective FGFR2 inhibitor in patients with FGFR2 mutations, including advanced cholangiocarcinoma. The trial will 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. Preliminary results from this trial are expected in 2025.

- Announced the addition of a potent and selective KRAS inhibitor to the pipeline. Preclinical data from this program as well as the Company’s H1047R mutant-selective PI3Kα clinical candidate were presented at the 2024 EORTC-NCI-AACR International Symposium on Molecular Targets and Cancer Therapeutics.
    - Mutations in KRAS are among the most prevalent mutations found in cancer, occurring most often in colorectal cancer, non-small cell lung cancer and pancreatic cancer. The first poster presented described Cogent’s internally-developed pan KRAS(ON) inhibitor with selectivity over HRAS and NRAS and picomolar (pM) activity across KRAS mutations without the potential liabilities of 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 CGT6737 is ongoing.
- The second poster highlighted Cogent's clinical candidate CGT6297, a potent allosteric inhibitor of PI3K, with 25-fold selectivity over PI3Kα WT. CGT6297 has 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. IND-enabling studies are expected to be initiated in 2025.

Anticipated Upcoming Milestones

- Complete enrollment in SUMMIT Part 2 in the first quarter of 2025 and deliver top-line results in the second half of 2025.
- Deliver top-line results from APEX in mid-2025.
- Deliver top-line results from PEAK by the end of 2025.

Upcoming Investor Conferences
A live webcast of the following events 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 events and will be archived for up to 30 days.

- Guggenheim Healthcare Innovation Conference, today, Tuesday, November 12, 2024 at 10:30 a.m. ET.
- Jefferies London Healthcare Conference on Wednesday, November 20, 2024 at 12:30 p.m. GMT (7:30 a.m. ET).
- Piper Sandler 35th Annual Healthcare Conference on Tuesday, December 4, 2024 at 9:30 a.m. ET.

Third Quarter 2024 Financial Results

Cash Position: As of September 30, 2024, cash, cash equivalents and marketable securities were $345.5 million, as compared to $389.9 million as of June 30, 2024. The company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements well past top-line results from SUMMIT, PEAK, and APEX registration-directed trials and into late 2026.

R&D Expenses: Research and development expenses were $63.6 million for the third quarter of 2024 as compared to $50.1 million for the third quarter of 2023. R&D expenses include non-cash stock compensation expense of $4.8 million for the third quarter of 2024 compared to $4.0 million for the third quarter of 2023. Increases resulted from costs associated with the acceleration of enrollment in PEAK, SUMMIT and the continued development of our research pipeline.

G&A Expenses: General and administrative expenses were $11.8 million for the third quarter of 2024 as compared to $9.5 million for the third quarter of 2023. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $5.6 million for the third quarter of 2024 compared to $4.8 million for the third quarter of 2023.

Net Loss: Net loss was $70.6 million for the third quarter of 2024 as compared to a net loss of $55.4 million for the same period of 2023.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)
Cogent also announced today that, on November 6, 2024, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grant of "inducement" equity awards to three new employees under the company's 2020 Inducement Plan with grant dates of November 6, 2024 and November 11, 2024. 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 132,350 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. 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, 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 potential for the company's pipeline programs targeting KRAS and PI3Kα to produce best-in-class assets; the expectation to deliver preliminary results from the company's Phase 1 study of CGT4859 in 2025; the expectation to initiate IND-enabling studies for CGT6297 in 2025; the expectation to complete enrollment in SUMMIT Part 2 in the first quarter of 2025 and deliver top-line results in the second half of 2025; the expectation to deliver top-line results from APEX in mid-2025; the expectation to deliver top-line results from PEAK by the end of 2025; the company's anticipated cash runway into late 2026 and planned presentations at upcoming scientific and investor conferences. 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 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 63,614	$ 50,127	$ 170,613	$ 125,036
General and administrative	11,800	9,453	31,592	24,866
Total operating expenses	75,414	59,580	202,205	149,902
Loss from operations	(75,414)	(59,580)	(202,205)	(149,902)
Other income:				
Interest income	4,779	4,198	14,229	9,207
Other income, net	1	—	44	950
Change in fair value of CVR liability	—	—	—	1,700
Total other income, net	4,780	4,198	14,273	11,857
Net loss	$ (70,634)	$ (55,382)	$ (187,932)	$ (138,045)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.64)	$ (0.64)	$ (1.85)	$ (1.79)
Weighted average common shares outstanding, basic and diluted	110,165,580	86,165,951	101,435,402	77,274,580

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 345,548	$ 273,170
Working capital	$ 288,480	$ 232,603
Total assets	$ 384,016	$ 313,437
Total liabilities	$ 69,357	$ 55,635
Total stockholders' equity	$ 314,659	$ 257,802

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