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

August 6, 2024

SUMMIT, PEAK and APEX registration-directed clinical trial enrollment remains on track; topline results expected from all three studies in 2025

Ended 2Q 2024 with $390 million, sufficient to fund operations into 2027

WALTHAM, Mass. and BOULDER, Colo., Aug. 06, 2024 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today reported financial results for the second quarter ended June 30, 2024.

“Cogent has made tremendous progress in the first half of 2024 and we look forward to continuing to execute on our key priorities across the portfolio,” said Andrew Robbins, the Company’s President and Chief Executive Officer. “All three of our bezuclastinib registration-directed trials remain on track and we expect to complete enrollment in our PEAK global Phase 3 trial this quarter, with topline data expected from all three trials in 2025. In parallel, our Research team continues to make excellent progress as we develop next-generation programs to build out our pipeline.”

Recent Business Highlights

- Announced alignment with the U.S. Food and Drug Administration (FDA) on the Company’s novel patient reported outcome measure, Mastocytosis Symptom Severity Daily Diary (MS2D2), for use in Part 2 of the registration-directed SUMMIT trial evaluating bezuclastinib in Nonadvanced Systemic Mastocytosis (NonAdvSM) patients.

- Announced additional clinical data from SUMMIT Part 1 at the 2024 European Hematology Association (EHA) Congress.
  - As of the cutoff date, December 18, 2023, patients in Part 1 treated at the recommended dose of 100 mg bezuclastinib demonstrated >90% reductions across all markers of mast cell burden. Additional data also showed meaningful reduction in symptom severity and objective measures of disease, including:
    - Substantial reduction in mast cell reactions (>50%) and patients’ most severe symptoms as measured by MS2D2.
    - Clinically meaningful reduction in all individual MS2D2 TSS symptoms and domains, as well as additional symptoms including dizziness, diarrhea severity, and brain fog.
    - Clinically meaningful improvement in skin symptoms as well as objective reduction in skin lesions.
  - Consistent with results previously reported, the recommended dose of 100 mg demonstrates a favorable safety and tolerability profile.

- Presented positive lead-in data from the ongoing Phase 3 PEAK trial at the 2024 ASCO annual meeting.
  - As of the cutoff date, April 1, 2024, 42 patients in Part 1 had been on study for a median of 15.3 months. The median progression-free survival (mPFS) during treatment with bezuclastinib and sunitinib was 10.2 months in all patients.
    - In a subset of patients with second-line gastrointestinal stromal tumors (GIST) with only prior imatinib, which most closely resembles patients currently enrolling in Part 2 of PEAK, the data demonstrate a mPFS of 19.4 months.
  - In addition, the objective response rate (ORR) in all patients treated with bezuclastinib and sunitinib was 27.5% and in the subset of second-line patients the ORR was 33.3%, per investigator assessment. Combination treatment resulted in a disease control rate of 80% in all patients and 100% in patients with prior imatinib only.
  - The combination of bezuclastinib and sunitinib does not appear to add to the severity of adverse events known to be associated with sunitinib monotherapy and is well-tolerated. The majority of treatment-emergent adverse events (“TEAEs”) were low-grade and reversible and discontinuations due to TEAEs remain limited.

- Announced a new Phase 2 clinical trial of bezuclastinib plus sunitinib in later line GIST patients, sponsored by the Sarcoma Alliance for Research through Collaboration (SARC) and in collaboration with The Life Raft Group and Dana-Farber Cancer Institute.

  - The open label, single-arm Phase 2 trial sponsored by SARC and in collaboration with The Life Raft Group and Dana-Farber Cancer Institute is designed to evaluate the mPFS as well as the safety and tolerability of

bezuclastinib plus sunitinib in 40 patients with GIST who have previously progressed on sunitinib.

- Appointed Cole Pinnow Chief Commercial Officer.
  - Mr. Pinnow joined Cogent from Pfizer, where he held increasing roles of responsibility, including President and Managing Director of Pfizer Canada and most recently as Global Franchise Lead, Genitourinary and Breast Cancer Business where he led a global commercial team accountable for the growth of a $5B innovative cancer portfolio in prostate, kidney, bladder and breast therapies. Prior to Pfizer, he held several leadership roles with Hospira and founded the company's commercial development organization. Mr. Pinnow began his pharmaceutical career as a scientist at Abbott Laboratories.

- Initiated IND-enabling studies for the potent, selective CNS-penetrant ErbB2 program following presentation of new preclinical data at the American Association for Cancer Research (AACR) 2024 Annual Meeting.
  - The poster described CGT4255's exceptional stability in human whole blood and liver cytosol fractions and high oral bioavailability and low clearance across preclinical species.
  - In addition, CGT4255 demonstrated 80% brain penetrance in mice and was well-tolerated at 10 fold maximally efficacious concentration, resulting in mouse tumor regression, suggesting potential best-in class performance.

Anticipated Upcoming Milestones

- Complete enrollment in the global, Phase 3 PEAK trial in patients with GIST in Q3 2024.
- Provide additional safety, tolerability, and patient-reported outcomes data from the open label extension portion of SUMMIT Part 1 by the end of 2024.
- Complete enrollment in the registration-directed APEX Phase 2 trial in patients with Advanced Systemic Mastocytosis (AdvSM) by the end of 2024 and report top-line results by mid-2025.
- Complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and deliver top-line results by the end of 2025.
- 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.
- Select lead candidate and initiate IND-enabling studies from ongoing PI3Kα program, designed to potently and selectively target the H1047R driver mutation, which affects >30,000 cancer patients each year.

Second Quarter 2024 Financial Results

Cash Position: As of June 30, 2024, cash, cash equivalents and marketable securities were $389.9 million, as compared to $435.7 million as of March 31, 2024. The company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into 2027 and through clinical readouts from ongoing SUMMIT, PEAK, and APEX registration-directed trials.

R&D Expenses: Research and development expenses were $54.3 million for the second quarter of 2024 as compared to $38.9 million for the second quarter of 2023. The increase was primarily due to costs associated with accelerating enrollment in both SUMMIT and PEAK clinical trials, on-going APEX costs and costs related to development of the research pipeline. R&D expenses include non-cash stock compensation expense of $4.7 million for the second quarter of 2024 as compared to $3.5 million for the second quarter of 2023. In the quarter, an additional $4.5 million was incurred to support sunitinib clinical supply for the PEAK trial due to faster than expected enrollment.

G&A Expenses: General and administrative expenses were $10.1 million for the second quarter of 2024 as compared to $8.2 million for the second quarter of 2023. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $5.3 million for the second quarter of 2024 as compared to $3.6 million for the second quarter of 2023.

Net Loss: Net loss was $59.0 million for the second quarter of 2024 as compared to a net loss of $44.1 million for the same period of 2023.

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 company's anticipated cash runway into 2027, the expectation to complete enrollment in the global Phase 3 PEAK trial in the third quarter of 2024 and to report top-line results by the end of 2025, the expectation to complete enrollment in the SUMMIT Part 2 trial in the second quarter of 2025 and to report top-line results by the end of 2025, the expectation to complete enrollment in the registration-directed APEX Phase 2 trial by the end of 2024 and to report top-line results mid-2025, the expectation to provide additional safety, tolerability and patient-reported outcomes data from the open label extension portion of SUMMIT Part 1 by the end of 2024, the expectation to initiate a Phase 1 trial of the

company's FGFR2 inhibitor with best-in-class potential in the second half of 2024, the expectation to select a lead candidate and initiate IND-enabling studies from the company's ongoing PI3Kα 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 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 54,294	$ 38,871	$ 106,999	$ 74,909
General and administrative	10,093	8,214	19,792	15,413
Total operating expenses	64,387	47,085	126,791	90,322
Loss from operations	(64,387)	(47,085)	(126,791)	(90,322)
Other income:				
Interest income	5,393	2,741	9,450	5,009
Other income, net	44	268	43	950
Change in fair value of CVR liability	—	—	—	1,700
Total other income, net	5,437	3,009	9,493	7,659
Net loss	$ (58,950)	$ (44,076)	$ (117,298)	$ (82,663)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.59)	$ (0.59)	$ (1.21)	$ (1.14)
Weighted average common shares outstanding, basic and diluted	99,240,030	74,753,269	97,022,345	72,755,210

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 389,904	$ 273,170
Working capital	$ 329,968	$ 232,603
Total assets	$ 429,935	$ 313,437
Total liabilities	$ 56,712	$ 55,635
Total stockholders' equity	$ 373,223	$ 257,802

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