Cogent Biosciences Reports Recent Business Highlights and Third Quarter 2023 Financial Results

November 2, 2023

SUMMIT and APEX clinical presentations planned for 2023 ASH Annual Meeting; SUMMIT NonAdvSM data selected for oral presentation

SUMMIT Part I completed upsized enrollment during Q3; SUMMIT Part 2 expected to begin in 1H 2024 at over 50 sites globally

33% ORR and >14 months median duration of treatment for 2nd-line GIST patients from updated PEAK lead-in data presented at 2023 CTOS Annual Meeting

Ended Q3 2023 with $312.8 million, providing cash runway into 2026

WALTHAM, Mass. and BOULDER, Colo., Nov. 02, 2023 (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, 2023.

"This quarter was marked by meaningful progress as we furthered our efforts developing bezuclastinib for the AdvSM, NonAdvSM and GIST patient populations," said Andrew Robbins, Cogent's President and Chief Executive Officer. "We look forward to the opportunity to present clinical data from both SUMMIT, selected for an oral presentation, and APEX clinical trials at the 2023 American Society of Hematology (ASH) annual meeting in December, and are pleased with the updated PEAK lead-in data we are sharing at the 2023 Connective Tissue Oncology Society (CTOS) annual meeting this weekend. With these important advances coupled with our cash runway into 2026, we believe we are well positioned to further build on our momentum to bring best-in-class therapies to patients with genetically defined diseases."

Business Highlights & Milestones

- Oral presentation of initial clinical data from SUMMIT Part 1a at the ASH annual meeting on Saturday, December 9, 2023. SUMMIT is a randomized, global, multicenter, double-blind, placebo-controlled, multi-part Phase 2 trial evaluating bezuclastinib in patients with nonadvanced systemic mastocytosis (NonAdvSM). Cogent will host an investor webcast to review the results on Monday, December 11, 2023 at 8:00 a.m. ET. Details will be provided closer to the event.
    - Presentation will include safety, tolerability, pharmacokinetics, biomarker and symptomatic improvement results from the 20 patients enrolled in SUMMIT Part 1a.
    - Measures of symptomatic improvement will include clinical data collected from multiple patient reported outcome measures including MAS, MCQoL, PGIS and PGIC.
    - SUMMIT Part 1 enrollment completed in Q3 2023, including over-enrollment at 54 patients across Part 1a and Part 1b. Clinical results from the entire Part 1 patient population are planned for presentation at a scientific conference in Q1 2024.
    - SUMMIT Part 2, a registration-directed, global, randomized placebo-controlled trial is on track for initiation in 1H 2024, ahead of schedule.

- Updated clinical data from the lead-in portion of the ongoing PEAK Phase 3 study to be shared in an oral presentation at the 2023 CTOS annual meeting on November 4, 2023. PEAK is an ongoing, multi-part Phase 3 randomized, global, multicenter trial evaluating bezuclastinib in combination with sunitinib in patients with imatinib-resistant gastrointestinal stromal tumors (GIST).
    - Safety and tolerability data from 42 patients enrolled in Part 1a and Part 1b are consistent with results shared at the 2023 American Society of Clinical Oncology (ASCO) annual meeting, demonstrating the combination of bezuclastinib and sunitinib was well tolerated and the adverse event profile was similar to sunitinib monotherapy.
    - Updated clinical activity from a subset of 2nd-line GIST patients demonstrates 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.
    - Phase 3 portion of the PEAK study remains on track to complete enrollment by the end of 2024, with over 100 active sites globally.

- Updated clinical results from Part 1 of the ongoing APEX study to be presented at the 2023 ASH annual meeting on Monday, December 11, 2023. APEX is a global, multi-part Phase 2 trial evaluating bezuclastinib in patients with advanced

systemic mastocytosis (AdvSM).
    - Presentation will include safety, tolerability, pharmacokinetics, biomarker and response assessments from 33 patients enrolled in APEX Part 1.
    - APEX Part 2 is on track to complete enrollment by the end of 2024. An additional APEX cohort was initiated in Q3 and is designed to allow concomitant administration of bezuclastinib with azacitadine in patients with systemic mastocytosis with an associated hematologic neoplasm (SM-AHN).

- Presented preclinical data at the 2023 ENA annual meeting on the Company's next-generation, reversible, non-covalent fibroblast growth factor receptor 2 (FGFR2) program, which exhibited low nanomolar 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 a mutant-driven mouse model, CGT4859 demonstrated dose-responsive tumor growth inhibition with complete regressions at 5 mg/kg PO and was well-tolerated. Cogent anticipates filing an Investigational New Drug (IND) Application and beginning a clinical trial in 2024.

Upcoming Scientific Presentations

- **2023 ASH - Oral Presentation**
  Title: Initial Results from Summit: An Ongoing, 3-Part, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase 2 Clinical Study of Bezuclastinib in Adult Patients with NonAdvanced Systemic Mastocytosis (NonAdvSM)
  Date: Saturday, December 9, 2023
  Session Time: 9:30 a.m. – 11:00 a.m. PT/12:30 p.m. – 2:00 p.m. ET
  Presenter: Dr. Prithviraj Bose, MD Anderson Cancer Center, Houston, Texas

- **2023 CTOS – Oral Presentation**
  Title: Peak Study: A Phase 3, Randomized, Open-Label, Multicenter Clinical Study of Bezuclastinib (CGT9486) and Sunitinib Combination Versus Sunitinib in Patients with Gastrointestinal Stromal Tumors (GIST)
  Date: November 4, 2023
  Session Time: 9:00 a.m. – 10:00 a.m. GMT/5:00 a.m. – 6:00 a.m. ET
  Presenter: Dr. Neeta Somaiah, MD Anderson Cancer Center, Houston, Texas

- **2023 ASH – Poster Presentation**
  Title: Safety and Efficacy of Bezuclastinib (CGT9486), a Novel, Highly Selective, Potent KIT D816V Tyrosine Kinase Inhibitor, in Patients with Advanced Systemic Mastocytosis (AdvSM): Results From Part 1 of the Phase 2 Apex Trial
  Date: Monday, December 11, 2023
  Session Time: 6:00 p.m. – 8:00 p.m. PT/9:00 p.m. – 11:00 p.m. ET
  Presenter: Dr. Pankit Vachhani, University of Alabama, Birmingham

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.

- Jefferies London Healthcare Conference on Wednesday, November 15, 2023 at 12:00 p.m. GMT (7:00 a.m. ET).
- Piper Sandler 35th Annual Healthcare Conference on Tuesday, November 28, 2023 at 2:30 p.m. ET.

Third Quarter 2023 Financial Results

Cash Position: As of September 30, 2023, cash, cash equivalents and marketable securities were $312.8 million, as compared to $350.9 million as of June 30, 2023. The company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into 2026.

R&D Expenses: Research and development expenses were $50.1 million for the third quarter of 2023 as compared to $29.9 million for the third quarter of 2022. R&D expenses include non-cash stock compensation expense of $4.0 million for the third quarter of 2023 compared to $2.1 million for the third quarter of 2022. In the quarter, $6.6 million in non-recurring charges were incurred for third party CDMOs to prepare for bezuclastinib pre-commercialization and to support sunitinib clinical supply for the PEAK study. Additional increases resulted from costs associated with the acceleration of APEX, SUMMIT and PEAK clinical trials and the continued development of our research pipeline.

G&A Expenses: General and administrative expenses were $9.5 million for the third quarter of 2023 as compared to $6.9 million for the third quarter of 2022. G&A expenses include non-cash stock compensation expense of $4.8 million for the third quarter of 2023 compared to $2.6 million for the third quarter of 2022.

Net Loss: Net loss was $55.4 million for the third quarter of 2023 as compared to a net loss of $35.1 million for the same period of 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 FGFR2 and ErbB2. 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: Twitter and LinkedIn. Information that may be important to investors will be routinely posted on our website and Twitter.

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: planned SUMMIT and APEX clinical presentations at the 2023 ASH annual meeting, the upcoming presentation of PEAK clinical data at the 2023 CTOS annual meeting, the expected initiation of SUMMIT Part 2 in 1H 2024, the company's anticipated cash runway into 2026, the company's mission of bringing best-in-class therapies to patients with genetically defined diseases, plans to present clinical results from all of SUMMIT Part 1 at a scientific conference in Q1 2024, the expectation that enrollment in both PEAK and APEX Part 2 will be completed by the end of 2024, and plans to file an IND and initiate a clinical trial for the company's FGFR2 program in 2024. 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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 50,127	$ 29,936	$ 125,036	$ 84,885
General and administrative	9,453	6,885	24,866	19,209
Total operating expenses	59,580	36,821	149,902	104,094
Loss from operations	(59,580)	(36,821)	(149,902)	(104,094)
Other income:				
Interest income	4,198	1,500	9,207	1,879
Other income, net	—	259	950	1,592
Change in fair value of CVR liability	—	—	1,700	—
Total other income, net	4,198	1,759	11,857	3,471
Net loss	$ (55,382)	$ (35,062)	$ (138,045)	$ (100,623)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.64)	$ (0.50)	$ (1.79)	$ (1.84)
Weighted average common shares outstanding, basic and diluted	86,165,951	69,576,359	$ 77,274,580	54,780,041

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 312,835	$ 259,276
Working capital	$ 251,234	$ 238,117
Total assets	$ 355,446	$ 300,810
Total liabilities	$ 52,548	$ 45,075
Total stockholders' equity	$ 302,898	$ 255,735

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