Cogent Biosciences Reports Recent Business Highlights and Second Quarter 2022 Financial Results

August 9, 2022

On-track to present additional data from Phase 2 APEX trial by the end of 2022

Initial data from Phase 2 SUMMIT trial & lead-in data from Phase 3 PEAK trial planned for 1H23

Ended 2Q 2022 with $325.6 million, including $172.6 million in gross proceeds from June 2022 public offering, sufficient to fund operations into 2025

CAMBRIDGE, Mass. and BOULDER, Colo., Aug. 09, 2022 (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, 2022.

“In the second quarter we achieved a number of important milestones as we continued to advance bezuclastinib and grow the research and development pipeline,” said Andrew Robbins, President and CEO of Cogent Biosciences. “Most notably, we reported positive initial clinical data from our APEX trial that strengthened our belief in bezuclastinib’s potential to provide meaningful clinical activity for systemic mastocytosis patients, without the tolerability challenges seen with other available treatment options. We remain on track to provide another clinical update from this trial by the end of 2022. We are equally excited about the opportunity with bezuclastinib in non-advanced systemic mastocytosis and gastrointestinal stromal tumor (GIST) patients and expect to provide clinical data updates on these programs during the first half of 2023. Based on the positive APEX data, we were able to secure additional financing at the end of the quarter, and we are confident this will support our go forward strategy into 2025.”

Recent Business Highlights

- In June 2022, Cogent reported positive initial data from its ongoing Phase 2 APEX clinical trial evaluating the selective KIT D816V inhibitor, bezuclastinib, in patients with advanced systemic mastocytosis (AdvSM).
    - As of the data cutoff date, May 24, 2022, all 11 patients treated were evaluated for signs of clinical activity. Bezuclastinib demonstrated rapid reductions in serum tryptase, with all patients achieving a ≥50% reduction (10/11 achieved within the first week of treatment) and 6/11 achieving serum tryptase <20ng/mL. All patients remained on treatment with treatment duration ranging from 0.5 - 4.8 months. Bezuclastinib was generally well-tolerated at all doses with no reported periorbital or peripheral edema, cognitive effects or intracranial bleeding events.

- In April 2022, the Company presented early data and outlined its strategy to create best-in-class small molecules from the company’s growing pipeline of novel, targeted therapy programs at the American Association of Cancer Research (AACR) annual meeting and company sponsored R&D investor event.
    - Announced plans to advance a potent, selective FGFR2 inhibitor toward candidate selection with a product profile that includes best-in-class selectivity against all known FGFR2 primary driver and secondary resistance mutations.
    - Announced development of an ErbB2 mutant selective inhibitor for patients with mutations that are not well addressed by therapies currently approved or in clinical development.

- Appointed Fang Fang, Ph.D., Vice President, Biometrics in Development Operations.

    - Dr. Fang joins Cogent with over 20 years of industry experience and leadership in oncology biometrics and biostatistics. Prior to joining, she was Vice President, Biometrics at Kiniksa Pharmaceuticals. Earlier in her career, Dr. Fang held roles of increasing responsibility at Merrimack Pharmaceuticals, Bayer Healthcare, Eisai Medical Research and Astellas Pharma. Dr. Fang received her Ph.D. in Biostatistics from Rutgers University.

Upcoming Milestones

- Present additional data from APEX, a global, multicenter Phase 2 clinical trial of bezuclastinib in patients with advanced systemic mastocytosis (AdvSM) by the end of 2022.

- Present initial data from SUMMIT, a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 clinical trial with bezuclastinib for nonadvanced systemic mastocytosis (NonAdvSM) in the first half of 2023.

- Present lead-in data from PEAK, a registrational randomized, open-label, global, Phase 3 clinical trial in patients with gastrointestinal stromal tumors (GIST), in the first half of 2023.

- File first internally developed Investigational New Drug application (IND) from Cogent's potent, selective FGFR2 inhibitor program in the second half of 2023.

Second Quarter 2022 Financial Results

Cash Position: As of June 30, 2022, cash and cash equivalents were $325.6 million, as compared to $191.0 million as of March 31, 2022. The company believes that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into 2025.

R&D Expenses: Research and development expenses were $29.5 million for the second quarter of 2022 as compared to $12.4 million for the second quarter of 2021. The increase was primarily due to costs associated with the on-going APEX, SUMMIT and PEAK clinical trials and costs related to expanding the Cogent Research Team, which was formed in the second quarter of 2021. R&D expenses include non-cash stock compensation expense of $2.1 million for the second quarter of 2022 compared to $1.0 million for the second quarter of 2021.

G&A Expenses: General and administrative expenses were $6.4 million for the second quarter of 2022 as compared to $4.9 million for the second quarter of 2021. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $2.4 million for the second quarter of 2021 compared to $1.6 million for the second quarter of 2021.

Net Loss: Net loss was $34.9 million for the second quarter of 2022 as compared to a net loss of $16.5 million for the same period of 2021.

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 Cambridge, 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 plans to present additional data from APEX by the end of 2022, plans to present initial data from SUMMIT and lead-in data from PEAK in the first half of 2023, the company's anticipated cash runway, bezuclastinib's potential to provide meaningful clinical activity for systemic mastocytosis patients without the tolerability challenges seen with other available treatment options, and plans to file an IND for a selective FGFR2 inhibitor in the second half of 2023. 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 Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings 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 AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	29,479	12,388	54,949	20,601
General and administrative	6,376	4,904	12,324	9,491
Total operating expenses	35,855	17,292	67,273	30,092
Loss from operations	(35,855)	(17,292)	(67,273)	(30,092)
Other income:				
Interest income	272	120	379	245
Other income	656	623	1,333	1,227
Change in fair value of CVR liability	—	—	—	343

Total other income	928	743	1,712	1,815
Net loss and comprehensive loss	$ (34,927)	$ (16,549)	$ (65,561)	$ (28,277)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.71)	$ (0.43)	$ (1.39)	$ (0.77)
Weighted average common shares outstanding, basic and diluted	49,388,936	38,441,729	47,259,261	36,670,353

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

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 325,562	$ 219,684
Working capital	$ 303,017	$ 205,556
Total assets	$ 366,052	$ 232,092
Total liabilities	$ 46,667	$ 17,908
Total stockholders' equity	$ 319,385	$ 214,184

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