



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

May 10, 2022

Initial bezuclastinib APEX data to be presented at the European Hematology Association (EHA) 2022 Annual Congress

Building a portfolio of discovery stage programs, creating potential best-in-class small molecule kinase inhibitors for genetically defined oncology indications and rare diseases

Ended 1Q 2022 with \$191.0 million in cash, sufficient to fund operations into 2024

CAMBRIDGE, Mass. and BOULDER, Colo., May 10, 2022 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced financial results for the first quarter ended March 31, 2022.

"We continue to make significant progress towards our strategic priorities for 2022," said Andrew Robbins, President and CEO of Cogent Biosciences. "We look forward to presenting initial clinical data from our APEX trial of bezuclastinib in advanced systemic mastocytosis patients at the annual EHA meeting this June. This presentation will include patient data from each dose cohort of bezuclastinib, including levels of serum tryptase, a validated biomarker of mast cell activity. We also continue to enroll patients in the SUMMIT and PEAK trials with bezuclastinib. In addition, our research team has rapidly advanced our pipeline with the addition of our FGFR2 and ErbB2 programs, each with clear differentiation from other programs in development and best-in-class potential. With these important advances, we believe we are well positioned to build on our momentum to bring important therapies to patients with genetically defined diseases."

Upcoming Milestones and Recent Business Highlights

- On track to report initial clinical data from APEX, a global, multicenter, Phase 2 clinical trial of bezuclastinib, a potent, highly selective, minimally brain-penetrant KIT mutant inhibitor in patients with Advanced Systemic Mastocytosis (AdvSM) in the second quarter of 2022.
 - Data to be presented at the European Hematology Association (EHA) 2022 Annual Congress will include safety and tolerability from patients across each dose cohort, as well as levels of serum tryptase, a validated biomarker of mast cell activity. The hybrid conference will take place in Vienna, Austria from June 9-12, 2022.
- Presented early data and outlined Cogent's 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 Cogent R&D investor event.
 - Advancing a potent, selective FGFR2 inhibitor toward candidate selection with a product profile that includes best-in-class selectivity and potency against all known FGFR2 primary driver and secondary resistance mutations. On track for first internally developed Investigational New Drug application (IND) in the second half of 2023.
 - 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.
- Shared additional nonclinical data demonstrating bezuclastinib's potential as a best-in-class KIT mutant inhibitor during the 2022 AACR annual meeting.
 - Presentations demonstrated bezuclastinib has a unique profile as a potent, mutant KIT inhibitor (including KIT D816V) with minimal brain penetration and no activity against related kinases including PDGFR, FLT3 and CSF1R, which have been linked to off-target toxicities including edema and pleural effusions.
- Actively enrolling patients in SUMMIT, a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 clinical trial with bezuclastinib for nonadvanced systemic mastocytosis (NonAdvSM).
 - SUMMIT is designed to evaluate the safety and efficacy of bezuclastinib in patients with moderate to severe Indolent Systemic Mastocytosis (ISM) or Smoldering Systemic Mastocytosis (SSM).
- Actively enrolling patients in PEAK, a registrational randomized, open-label, global, Phase 3 clinical trial in patients with Gastrointestinal Stromal Tumors (GIST).
 - PEAK is designed to evaluate the efficacy and safety of bezuclastinib in combination with sunitinib compared to sunitinib alone in patients with locally advanced, unresectable or metastatic GIST who have received prior treatment with imatinib.

First Quarter 2022 Financial Results

- **Cash and Cash Equivalents:** As of March 31, 2022, cash and cash equivalents were \$191.0 million as compared to \$219.7 million as of December 31, 2021. Based on its current plans, the company expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into 2024.
- **R&D Expenses:** Research and development expenses were \$25.5 million for the first quarter of 2022 compared to \$8.2 million for the first 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.
- **G&A Expenses:** General and administrative expenses were \$5.9 million for the first quarter of 2022 compared to \$4.6 million for the first quarter of 2021. The increase was primarily due to the growth of the organization.
- **Net Loss:** Net loss was \$30.6 million for the first quarter of 2022 compared to a net loss of \$11.7 million for the first quarter 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 the company's anticipated cash runway, the presentation of initial clinical data from APEX at EHA in June 2022, the best-in-class potential of the company's research programs, including its FGFR2 and ErbB2 programs, and clinical development and regulatory plans and timelines, including the plan to file an IND in the second half of 2023 for the company's FGFR2 inhibitor candidate. 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)
(unaudited)

	Three Months Ended	
	March 31,	
	2022	2021
Operating expenses:		
Research and development	25,470	8,213
General and administrative	5,948	4,587
Total operating expenses	<u>31,418</u>	<u>12,800</u>

Loss from operations	(31,418)	(12,800)
Other income:		
Interest income	107	125
Other income	677	604
Change in fair value of CVR liability	—	343
Total other income	784	1,072
Net loss	<u>\$ (30,634)</u>	<u>\$ (11,728)</u>

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

	<u>March 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Cash and cash equivalents	\$ 191,047	\$ 219,684
Working Capital	\$ 176,854	\$ 205,556
Total assets	\$ 206,869	\$ 232,092
Total liabilities	\$ 19,006	\$ 17,908
Total stockholders' equity	\$ 187,863	\$ 214,184

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