Cogent Biosciences Provides Corporate Updates, Fourth Quarter and Full Year 2021 Financial Results

March 15, 2022

APEX, SUMMIT and PEAK bezuclastinib clinical trials actively enrolling patients

APEX initial clinical data presentation expected in the first half of 2022

R&D Investor Event planned for April 8, 2022

Ended 2021 with $219.7 million in cash, sufficient to fund operations into 2024

CAMBRIDGE, Mass. and BOULDER, Colo., March 15, 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 fourth quarter and year ended December 31, 2021.

“In 2021, Cogent achieved substantial progress toward our goal of establishing bezuclastinib as a best-in-class KIT mutant inhibitor for systemic mastocytosis and gastrointestinal stromal tumor (GIST) patients,” said Andrew Robbins, President and CEO of Cogent Biosciences. “All three late-stage bezuclastinib clinical trials are actively enrolling patients, and we look forward to presenting initial clinical data from APEX in the first half of 2022. In addition, we are excited about the progress the Cogent Research Team has made to date and look forward to sharing further details on bezuclastinib, as well as our growing portfolio, at our upcoming R&D Investor Event.”

Key Clinical, Research and Corporate Highlights

- **Cogent’s highly potent and selective KIT mutant inhibitor, bezuclastinib, is now under investigation in three late-stage clinical trials:**
  - **APEX: on track for initial clinical data readout in the first half of 2022**
    Cogent is currently enrolling APEX, a global, multicenter, Phase 2 clinical trial of bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM) and expects to report initial clinical data at a scientific conference during the first half of 2022, including levels of serum tryptase, a validated biomarker of mast cell activity. Learn more about the APEX trial at cogentclinicaltrials.com/APEX.
  - **SUMMIT: initiated in patients with Nonadvanced Systemic Mastocytosis (NonAdvSM)**
    Cogent is currently enrolling SUMMIT, a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 clinical trial. The study is designed to explore the safety and efficacy of bezuclastinib in patients with moderate to severe Indolent Systemic Mastocytosis (ISM) or Smoldering Systemic Mastocytosis (SSM). Learn more about the SUMMIT trial at cogentclinicaltrials.com/SUMMIT.
  - **PEAK: initiated in patients with Gastrointestinal Stromal Tumors (GIST)**
    During the fourth quarter of 2021, Cogent initiated and now is currently enrolling PEAK, a randomized, open-label, global, Phase 3 clinical trial. The PEAK study is designed to explore the efficacy 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. Learn more about the PEAK trial at cogentclinicaltrials.com/PEAK.

- **Preclinical data presented during the third quarter of 2021 highlights bezuclastinib as a potent KIT inhibitor with minimal CNS penetration and which avoids PDGFR inhibition:**
  - Cogent presented preclinical data providing further evidence of bezuclastinib as a differentiated, potent, and selective KIT mutant inhibitor with minimal brain penetration while avoiding inhibition of PDGFR isoforms. These data were presented in a virtual poster at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics.

- **Cogent Research Team created to generate robust pipeline of potential best-in-class small molecules**
  - **Cogent Research Team:** In 2021, we founded a highly-experienced Boulder-based discovery and research team focused on pioneering best-in-class, small molecule therapeutics to expand Cogent's pipeline. John Robinson, PhD, leads the Cogent Research Team, which has grown to over 35 employees and will move into its newly-built, state-of-the-art research facility in Boulder this spring.

- **R&D Investor Event:** Cogent will host an R&D Investor Event at which the Cogent Research Team will share additional nonclinical data demonstrating bezuclastinib's potential as a best-in-class KIT mutant inhibitor, outline its strategy and focus to create best-in-class small molecules, and present early data from its growing pipeline of novel, small molecule targeted therapy programs including FGFR2. The R&D Investor Event will be a live webcast on Friday, April 8, 2022 beginning at 4:05 p.m. ET. On the day of the webcast, the American Association for Cancer Research (AACR) poster presentations will be made available through the AACR conference website at 1:00 p.m. ET. Additional details about the R&D Investor Event will be shared in the coming weeks.

- **Successfully bolstered Cogent balance sheet utilizing our At-The-Market (ATM) Program:** In Q4 2021, pursuant to Cogent's ATM program, we completed the sale of common shares to certain institutional investors for net proceeds of approximately $38 million with offering prices ranging between $9.25 and $10.30 per share.

- **Appointed Zamaneh Mikhak, MD as Senior Vice President, Head of Clinical Development**
    - Dr. Mikhak joins as an allergist/immunologist and physician scientist with over 20 years of experience in clinical practice and basic and translational research. Prior to joining Cogent, she held several leadership roles with increasing responsibilities, most recently leading clinical stage programs at both Boston Pharmaceuticals and Kiniksa Pharmaceuticals. Dr. Mikhak was an Assistant Professor at Harvard Medical School and an NIH funded Principal Investigator at Massachusetts General Hospital prior to joining industry. She earned her MD from the Perelman School of Medicine at the University of Pennsylvania and her Bachelor of Arts degree in Biology from Boston University.

- **Appointed Lei Sun, PhD as Vice President, Clinical Pharmacology & Translational Medicine**
    - Dr. Sun joins with over 20 years of industry experience with demonstrated leadership in clinical pharmacology, translational medicine, and DMPK in multiple therapeutic areas. Prior to joining Cogent, she was Head of Clinical Pharmacology at Alkermes. Earlier in her career, Dr. Sun held several roles of increasing responsibility at Ziopharm Oncology, Alnylam Pharmaceuticals, and Wyeth/Pfizer. Dr. Sun received her PhD in Chemistry & Chemical Biology and MS in Chemical & Biochemical Engineering from Rutgers University and her BS in Material Sciences & Engineering from Tianjin University in China.

- **Appointed Lora Marden as Vice President, Patient Advocacy, Engagement and Innovation**
    - Ms. Marden joins with over 15 years of rare disease biopharmaceutical and social services experience. Prior to joining Cogent, Ms. Marden was the Head of Global Patient Advocacy & Engagement at Kiniksa Pharmaceuticals. Previously, she held roles of increasing leadership responsibility in the areas of marketing, patient advocacy, medical affairs, commercial operations, and patient services at Sanofi-Genzyme, Alnylam Pharmaceuticals, and Sobi Inc., including contributing to the launch of multiple rare disease therapies. She currently sits as a Board Member for the MassBioEd Foundation and holds a Bachelor of Arts in Psychology from the University of Rochester.

Fourth Quarter and Year End 2021 Summarized Financial Results

- **R&D Expenses:** Research and development expenses were $20.5 million for the fourth quarter of 2021 and $55.9 million for the year ended December 31, 2021, as compared to $6.1 million for the fourth quarter of 2020 and $25.7 million for the year ended December 31, 2020. These expenses included trial start-up costs associated with SUMMIT and PEAK and initial costs related to expanding the Cogent Research Team.

- **G&A Expenses**: General and administrative expenses were $5.1 million for the fourth quarter of 2021 and $19.6 million for the year ended December 31, 2021, as compared to $5.3 million for the fourth quarter of 2020 and $17.4 million for the year ended December 31, 2020.

- **Net Loss:** Net loss was $24.9 million for the fourth quarter of 2021 and $72.3 million for the year ended December 31, 2021, as compared to a net loss of $11.3 million for the fourth quarter of 2021 and $74.8 million for the year ended December 31, 2020.

- **Cash and Cash Equivalents:** As of December 31, 2021, Cogent had cash and cash equivalents of $219.7 million. The company believes that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into 2024.

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. 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 expectation to present preliminary clinical data from APEX in the first half of 2022, the company's planned R&D investor event in April 2022, the anticipated move for the Cogent Research Team into its newly-built, state-of-the-art research facility in Boulder this spring, and the expectation that the company's AACR poster presentations will be made available through the AACR conference website on schedule. 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.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Collaboration revenue	$ —	$ —	$ —	$ 7,871
Operating expenses:				
Research and development	20,514	6,107	55,913	25,738
General and administrative	5,125	5,348	19,638	17,422
Acquired in-process research and development	—	—	—	46,910
Total operating expenses	25,639	11,455	75,551	90,070
Loss from operations	(25,639)	(11,455)	(75,551)	(82,199)
Other income:				
Interest income	106	70	467	144
Gain on disposal of long-lived assets	—	31	—	7,493
Other income	621	531	2,468	779
Change in fair value of CVR liability	—	(516)	343	(1,025)
Total other income	727	116	3,278	7,391
Net loss	$ (24,912)	$ (11,339)	$ (72,273)	$ (74,808)

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

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 219,684	$ 242,190
Working Capital	$ 205,556	$ 231,818
Total assets	$ 232,092	$ 250,916
Total liabilities	$ 17,908	$ 16,249
Total stockholders' equity	$ 214,184	$ 234,667

MEDIA CONTACT: Amanda Sellers asellers@vergescientific.com