# Cogent Biosciences Reports Recent Business Highlights and Third Quarter 2022 Financial Results

November 14, 2022

*Phase 3 PEAK trial initiated comparing bezuclastinib + sunitinib vs. sunitinib alone in second line gastrointestinal stromal tumor (GIST) patients; initial safety and pharmacokinetic data from lead-in phase to be presented at CTOS 2022*

*Phase 2 APEX trial in Advanced Systemic Mastocytosis (AdvSM); oral presentation at ASH 2022 including assessment of patient response*

*Developed an optimized formulation of bezuclastinib with new dosage strength and over 40% improvement in clinical exposure; potential to extend patent protection into 2043*

*Ended 3Q 2022 with $289.1 million, providing cash runway into 2025*

WALTHAM, Mass. and BOULDER, Colo., Nov. 14, 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 third quarter ended September 30, 2022.

"We are excited to announce the initiation of our Phase 3 PEAK trial in imatinib-resistant, second line GIST patients and look forward to presenting an update from our Phase 2 APEX trial in ASM patients in an oral presentation at ASH 2022," said Andrew Robbins, President and CEO of Cogent Biosciences. "Our team has made tremendous progress this year, advancing our three bezuclastinib clinical trials, PEAK, APEX, and SUMMIT, recently presenting new data on our novel FGFR2 and ErbB2 selective programs, and delivering an optimized formulation of bezuclastinib which will significantly improve the patient experience."

**Recent Business Highlights**

- Initiated the randomized portion of PEAK, a global Phase 3 clinical trial in GIST patients who have progressed following imatinib therapy. The trial is designed to explore the efficacy of bezuclastinib in combination with sunitinib compared to sunitinib alone.
    - The experimental arm of the PEAK trial includes a 600 mg daily dose of an optimized formulation of bezuclastinib, supplied as 75 mg tablets, which in the lead-in portion of the study demonstrated clinical exposures equivalent to the 1,000 mg daily dose of the original formulation used in the GIST Phase 1/2 clinical trial.

- Presented preclinical data at the EORTC-NCI-AACR (ENA) annual meeting on a next-generation fibroblast growth factor receptor 2 (FGFR2) program, which retains potency across all primary, gatekeeper and molecular brake resistance mutations, including N549K and V564I, while sparing FGFR1 inhibition. This program remains on track for IND in 2023, with IND-enabling activities to commence early next year.

- Presented preclinical data at ENA on a novel ErbB2 mutant selective program which demonstrates robust cellular inhibition of all key resistance and primary driver mutations, including L755S, V842I and S310F/Y, while sparing wild type EGFR target engagement.

**Upcoming Milestones**

- Present updated clinical data from APEX, a global, multicenter Phase 2 clinical trial of bezuclastinib in patients with advanced systemic mastocytosis (AdvSM) in an oral presentation at the 64th American Society of Hematology (ASH) Annual Meeting on Sunday, December 11, 2022. The presentation will include measures of clinical activity, including initial patient response assessment, in addition to pharmacokinetic and safety data. Cogent will host an investor webcast on December 12, 2022 at 8:00 am ET to discuss these data.
    - **Preliminary Safety and Efficacy from Apex, a Phase 2 Study of Bezuclastinib (CGT9486), a Novel, Highly Selective, Potent KIT D816V Tyrosine Kinase Inhibitor, in Adults with Advanced Systemic Mastocytosis (AdvSM)**
      **Presenter:** Daniel DeAngelo, M.D., Ph.D., Chief of the Division of Leukemia at the Dana-Farber Cancer Institute

- Present initial safety and pharmacokinetic data from the PEAK lead-in study at the Connective Tissue Oncology Society (CTOS) annual meeting, November 16-19, 2022.
    - **Peak Study: A Phase 3 Randomized, Open-label, Multicenter Clinical Study of Bezuclastinib (CGT9486) and Sunitinib Versus Sunitinib in Patients with Gastrointestinal Stromal Tumors**
      **Presenter**: Andrew J. Wagner, MD, Ph.D., Associate Chief Medical Officer at the Dana Farber Cancer Institute

- Present initial clinical efficacy results from refractory GIST patients receiving bezuclastinib plus sunitinib in the PEAK lead-in study during first half of 2023.

- Present initial clinical data from SUMMIT, a randomized, double-blind, placebo-controlled, global, multicenter, Phase 2 clinical trial of bezuclastinib in patients with nonadvanced systemic mastocytosis (NonAdvSM), now in the second half of 2023. Based on the exciting performance of bezuclastinib's optimized formulation in the PEAK lead-in trial, as well as in a separate healthy volunteer study, the SUMMIT trial protocol will be amended to allow for the optimized formulation to be introduced during the dose exploration phase.

- Begin IND enabling studies for a potentially best-in-class, FGFR1-sparing, pan-FGFR2 mutation tyrosine kinase inhibitor in early 2023. This program is Cogent's first internally developed research program and has been designed to overcome the clinical challenges of emergent FGFR2 treatment resistance, including the gatekeeper and molecular brake mutations that are the most common drivers of resistance, as well as off-target FGFR1 related adverse events that may limit the use of currently available and development stage FGFR2 tyrosine kinase inhibitors.

**Third Quarter 2022 Financial Results**

**Cash Position:** As of September 30, 2022, cash, cash equivalents and marketable securities were $289.1 million, as compared to $325.6 million as of June 30, 2022. The company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into 2025. During the third quarter of 2022 Cogent incurred one-time cash payments of $8.6 million mainly related to the build-out and equipment costs associated with its newly-constructed Research Lab in Boulder, CO.

**R&D Expenses:** Research and development expenses were $29.9 million for the third quarter of 2022 as compared to $14.8 million for the third quarter of 2021. R&D expenses include non-cash stock compensation expense of $2.1 million for the third quarter of 2022 compared to $1.4 million for the third quarter of 2021. Additional increases resulted from costs associated with the APEX, SUMMIT and PEAK clinical trials as well as 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 $6.9 million for the third quarter of 2022 as compared to $5.0 million for the third quarter of 2021. G&A expenses include non-cash stock compensation expense of $2.6 million for the third quarter of 2022 compared to $2.0 million for the third quarter of 2021.

**Net Loss:** Net loss was $35.1 million for the third quarter of 2022 as compared to a net loss of $19.1 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 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: discussion of the company's business and operations; projected cash runways; future product development plans; clinical development plans and timelines including anticipated data presentations from each of the APEX, SUMMIT and PEAK trials; the anticipated benefits of the new formulation of bezuclastinib and the potential to expand patent protection into 2043; and the productivity of the company's research pipeline and the expectation to file an IND in 2023 for an FGFR2 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 Quarterly Report on Form 10-Q 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**
*(in thousands, except share and per share amounts)*
*(unaudited)*

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |

| | | | | |
|---|---|---|---|---|
| Operating expenses: | | | | |
| Research and development | 29,936 | 14,798 | 84,885 | 35,399 |
| General and administrative | 6,885 | 5,021 | 19,209 | 14,512 |
| Total operating expenses | 36,821 | 19,819 | 104,094 | 49,911 |
| Loss from operations | (36,821) | (19,819) | (104,094) | (49,911) |
| Other income: | | | | |
| Interest income | 1,500 | 115 | 1,879 | 360 |
| Other income, net | 259 | 620 | 1,592 | 1,847 |
| Change in fair value of CVR liability | — | — | — | 343 |
| Total other income, net | 1,759 | 735 | 3,471 | 2,550 |
| Net loss | $ (35,062) | $ (19,084) | $ (100,623) | $ (47,361) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.50) | $ (0.48) | $ (1.84) | $ (1.25) |
| Weighted average common shares outstanding, basic and diluted | 69,576,359 | 39,848,943 | 54,780,041 | 37,741,526 |

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

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 289,094 | $ 219,684 |
| Working capital | $ 272,866 | $ 205,556 |
| Total assets | $ 331,560 | $ 232,092 |
| Total liabilities | $ 41,618 | $ 17,908 |
| Total stockholders' equity | $ 289,942 | $ 214,184 |

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