Cogent Biosciences Provides Corporate Updates and Reports Third Quarter 2021 Financial Results

November 10, 2021

Initiated SUMMIT, a Phase 2 clinical trial of bezuclastinib for Nonadvanced Systemic Mastocytosis (NonAdvSM) patients

PEAK, a Phase 3 clinical trial of bezuclastinib and sunitinib for Gastrointestinal Stromal Tumor (GIST) patients, remains on track for 2021 start following positive FDA discussions

Presented new preclinical data demonstrating bezuclastinib as a differentiated KIT inhibitor with minimal brain penetration

Ended Q3 2021 with $202.9 million in cash, sufficient to fund operations into 2024

CAMBRIDGE, Mass. and BOULDER, Colo., Nov. 10, 2021 /PRNewswire/ -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today announced financial results for the third quarter ended September 30, 2021 and provided corporate updates.

"We are pleased to announce that we have started the SUMMIT trial, a Phase 2 study of bezuclastinib in patients with nonadvanced systemic mastocytosis," said Andrew Robbins, President and CEO of Cogent Biosciences. "Based on recently presented preclinical data, we believe that bezuclastinib has best-in-class potential as a highly potent and selective KIT mutant inhibitor and look forward to initiating the PEAK trial for GIST patients in the coming weeks."

Recent Program and Corporate Highlights

- **SUMMIT trial initiated in NonAdvSM patients**
  - Cogent initiated 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).
  - SUMMIT is designed in three parts. Part 1 will enroll approximately 48 patients across 3 dose cohorts, plus one placebo arm, and is designed to confirm the optimal bezuclastinib dose. In addition, Part 1 will serve to validate a patient-reported outcomes (PRO) tool for use in assessing efficacy during Part 2 of the trial. Part 2 of SUMMIT will be randomized, double-blind, and placebo-controlled at a single dose level and will include a primary endpoint of disease improvement using the PRO tool from Part 1. After participation in Part 1 or Part 2, all patients may receive bezuclastinib in a long-term extension.
  - Learn more about the SUMMIT trial at cogentclinicaltrials.com
- **APEX trial on track for preliminary clinical data readout in the first half of 2022**
  - Cogent is currently enrolling APEX, a Phase 2 clinical trial of bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM) and expects to report preliminary 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.
- **PEAK trial of bezuclastinib and sunitinib for GIST patients to start in 2021**
  - Following recent positive interactions with the FDA, Cogent remains on track to initiate PEAK, a Phase 3 clinical trial of bezuclastinib in combination with sunitinib in imatinib-resistant GIST patients, during 2021.
- **Announces updated bezuclastinib formulation in partnership with Serán Biosciences**

    - Leveraging Serán's expertise in formulation and process optimization, an updated formulation of bezuclastinib has been developed. This formulation is expected to reduce the number of daily tablets, improving the overall patient experience.
    - Updated formulation will be used in PEAK trial beginning in 2021.
- **Presented new preclinical data supporting bezuclastinib as potential best-in-class KIT inhibitor**
    - Preclinical data presented at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics showed further evidence of bezuclastinib as a differentiated, potent, and selective KIT inhibitor.
        - In head-to-head studies comparing several commercial and development-stage KIT mutant inhibitors, bezuclastinib demonstrated minimal activity against closely related kinases, including PDGFR.
        - In a nonclinical safety pharmacology study in rodents, bezuclastinib demonstrated minimal brain penetration with a low brain-to-plasma ratio.
- **Appointed Dana Martin as Chief Patient Officer & Senior Vice President, Medical Affairs**
    - Dr. Martin joins with over 20 years of experience in the biopharmaceutical industry. Prior to joining Cogent, he held several roles of increasing leadership responsibility in the areas of clinical pharmacy, medical affairs, and patient advocacy at Genzyme Corporation, Synageva BioPharma, Sarepta Therapeutics, and Kiniksa Pharmaceuticals. Dr. Martin has contributed to the clinical development and/or product launch of multiple rare disease therapeutics, including first-to-market treatments for Fabry disease, Pompe disease, lysosomal acid lipase deficiency, and Duchenne muscular dystrophy. He holds a Bachelor of Science in pharmacy and a Doctor of Pharmacy from Massachusetts College of Pharmacy-Boston.
- **Appointed Courtney Watson as Vice President of Clinical Development Operations**
    - Mrs. Watson joins Cogent with nearly 15 years of experience in the biopharmaceutical industry. Prior to joining Cogent, Mrs. Watson was the Head of Clinical Operations at Fusion Pharmaceuticals. Previously, she served in various Clinical Operations roles of increasing responsibility at Forma Therapeutics, Synageva BioPharma, and Ziopharm Oncology. Mrs. Watson holds a Bachelor of Arts from the University of Southern Maine.

Third Quarter 2021 Summarized Financial Results

- **R&D Expenses:** Research and development expenses were $14.8 million for the third quarter of 2021 as compared to $5.0 million for the third quarter of 2020. Research and development expenses include non-cash stock compensation expense of $1.4 million for the third quarter of 2021 compared to $1.9 million for the third quarter of 2020.
- **G&A Expenses**: General and administrative expenses were $5.0 million for the third quarter of 2021 as compared to $5.6 million for the third quarter of 2020. General and administrative expenses include non-cash stock compensation expense of $2.0 million for the third quarter of 2021 compared to $1.6 million for the third quarter of 2020.
- **Net Loss:** Net loss was $19.1 million for the third quarter of 2021 as compared to a net loss of $50.0 million for the third quarter of 2020, which included $46.9 million resulting from the accounting treatment related to the asset acquisition of Kiq LLC. During the third quarter of 2021, the company spent $15.2 million of its cash and cash equivalents.
- **Cash and Cash Equivalents:** As of September 30, 2021, Cogent had cash and cash equivalents of $202.9 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 newly formed 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: discussion of the company's business and operations; projected cash runways; future product development plans; clinical development plans and timelines for its lead program, bezuclastinib, including the expectation to initiate the PEAK trial before the end of 2021, as well as the anticipated timeline for reporting clinical data from the APEX trial in 2022; the potential for bezuclastinib to be a best-in-class KIT mutant inhibitor; and the expected benefits of the updated bezuclastinib formulation planned for use in the PEAK trial. 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

Cogents' 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	$ —	$ 312	$ —	$ 7,871
Operating expenses:				
Research and development	14,798	5,003	35,399	19,630
General and administrative	5,021	5,598	14,512	12,074
Acquired in-process research and development	—	46,910	—	46,910
Total operating expenses	19,819	57,511	49,911	78,614
Loss from operations	(19,819)	(57,199)	(49,911)	(70,743)
Other income:				
Interest income	115	23	360	73
Gain on disposal of long-lived assets	—	7,463	—	7,470
Other income	620	239	1,847	239
Change in fair value of CVR liability	—	(509)	343	(509)
Total other income	735	7,216	2,550	7,273
Net loss and comprehensive loss	$ (19,084)	$ (49,983)	$ (47,361)	$ (63,470)

COGENT BIOSCIENCES, INC.
CONSOLIDATED SELECTED BALANCE SHEET DATA
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 202,888	$ 242,190
Working capital	$ 190,795	$ 231,818
Total assets	$ 215,385	$ 250,916
Total liabilities	$ 18,147	$ 16,249
Total stockholders' equity	$ 197,238	$ 234,667

View original content to download multimedia:https://www.prnewswire.com/news-releases/cogent-biosciences-provides-corporate-updates-and-reports-third-quarter-2021-financial-results-301420944.html

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