Cogent Biosciences Reports First Quarter 2024 Financial Results

May 7, 2024

SUMMIT, PEAK and APEX registration-directed clinical trial enrollment remains on track; topline results expected from all three studies in 2025

Ended 1Q 2024 with $435.7 million in cash, sufficient to fund operations into 2027

WALTHAM, Mass. and BOULDER, Colo., May 07, 2024 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today provided a business update and announced financial results for the first quarter ended March 31, 2024.

“Our team made important progress in the first quarter,” said Andrew Robbins, the Company’s President and Chief Executive Officer. “Based on the emerging clinical results demonstrating the potential of bezuclastinib in both systemic mastocytosis and GIST patients, we have experienced very strong interest in our ongoing clinical trials from patients and investigators. We remain on track to complete enrollment in APEX and PEAK by the end of this year, and to complete enrollment in SUMMIT during 2Q 2025. This should allow us to report topline results from all three registration-directed trials during 2025. Following our successful financing in February, we are well positioned with a cash runway into 2027, allowing us to complete our ongoing studies while continuing to broaden our portfolio with a robust research pipeline of novel compounds.”

Recent Business Highlights

- Reported positive Part 1b data from the Company’s ongoing SUMMIT trial evaluating bezuclastinib in patients with nonadvanced systemic mastocytosis (NonAdvSM) at the 2024 American Academy of Allergy Asthma & Immunology Annual Meeting (AAAAI) meeting and initiated the registration-directed SUMMIT Part 2.
    - Selected the 100 mg once-daily recommended Phase 2 dose (RP2D) based on:
        - 51% week 12 mean improvement in Total Symptom Score (TSS), including 70% of patients achieving ≥50% reduction in TSS at week 12
        - 49% week 12 mean improvement in quality-of-life (MC-QoL)
        - Safety and tolerability profile generally similar to placebo with no grade 3/4 events, and no bleeding, edema or cognitive events, no dose reductions and no discontinuations
- Presented preclinical data from the company’s ErbB2 candidate at the American Association of Cancer Research (AACR) annual meeting.
    - The new preclinical data described CGT4255’s exceptional stability in human whole blood and liver cytosol fractions, high oral bioavailability and low clearance across preclinical species. CGT4255 also demonstrated 80% brain penetrance in mice and was well-tolerated at 10x maximally efficacious concentration, resulting in mouse tumor regression, suggesting potential best-in-class properties.
- Completed oversubscribed private placement, resulting in $213.4 million net proceeds, extending the company’s cash runway into 2027.

Upcoming Milestones

- Share updated clinical data from the lead-in portion of the PEAK trial at the American Society of Clinical Oncology (ASCO) annual meeting taking place May 31-June 4, 2024. PEAK is the Company’s ongoing Phase 3 trial evaluating bezuclastinib in combination with sunitinib in patients with Gastrointestinal Stromal Tumors (GIST). Cogent remains on track to complete enrollment in PEAK by the end of 2024 and report top-line results by the end of 2025.

  ASCO Poster details
  Title: Peak part 1 summary: A phase 3, randomized, open-label multicenter clinical study of bezuclastinib (CGT9486) and sunitinib combination versus sunitinib in patients with gastrointestinal stromal tumors (GIST)
  Session Type and Title: Poster Session – Sarcoma
  Session Date and Time: June 1, 2024, 1:30 PM-4:30 PM CDT

- Complete enrollment in APEX in patients with advanced systemic mastocytosis (AdvSM) by the end of 2024 and report top-line results mid-2025.

- Complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and report top-line results by the end of 2025.

First Quarter 2024 Financial Results

Cash and Cash Equivalents: As of March 31, 2024, cash, cash equivalents and marketable securities were $435.7 million as compared to $273.2 million as of December 31, 2023. Total cash spend in the quarter was $51.2 million, including a non-recurring payment of $8.6 million related to annual performance-based bonus compensation. Based on its current plans, the company expects its existing cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into 2027 and through clinical readouts from ongoing SUMMIT, PEAK, and APEX registration-directed trials.

R&D Expenses: Research and development expenses were $52.7 million for the first quarter of 2024 compared to $36.0 million for the first quarter of 2023. The increase was primarily due to costs associated with accelerating enrollment in both SUMMIT and PEAK clinical trials, on-going APEX costs and costs related to development of the research pipeline. R&D expenses include non-cash stock compensation expense of $4.4 million for the first quarter of 2024 as compared to $3.0 million for the first quarter of 2023.

G&A Expenses: General and administrative expenses were $9.7 million for the first quarter of 2024 compared to $7.2 million for the first quarter of 2023. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $5.0 million for the first quarter of 2024 as compared to $2.9 million for the first quarter of 2023.

Net Loss: Net loss was $58.3 million for the first quarter of 2024 compared to a net loss of $38.6 million for the first quarter of 2023.

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 mutations in FGFR2, ErbB2 and PI3Kα. 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: X (formerly known as Twitter) and LinkedIn. Information that may be important to investors will be routinely posted on our website and X.

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 clinical development plans and timelines, including the expectation to complete enrollment in APEX by the end of 2024 and to report top-line results mid-2025, the expectation to complete enrollment in SUMMIT Part 2 in the second quarter of 2025 and to report top-line results by the end of 2025, the expectation to complete enrollment in PEAK by the end of 2024 and to report top-line results by the end of 2025, plans to share updated clinical data from the lead-in portion of PEAK at the ASCO annual meeting in the second quarter of 2024, the Company's projected cash runway into 2027, the therapeutic potential of bezuclastinib in both systemic mastocytosis and GIST patients, and the potential best-in-class properties of the Company's preclinical ErbB2 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
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 52,705	$ 36,038

General and administrative	9,699	7,199
Total operating expenses	62,404	43,237
Loss from operations	(62,404)	(43,237)
Other income:		
Interest income	4,057	2,268
Other income, net	(1)	682
Change in fair value of CVR liability	—	1,700
Total other income, net	4,056	4,650
Net loss	$ (58,348)	$ (38,587)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.62)	$ (0.55)
Weighted average common shares outstanding, basic and diluted	94,804,659	70,734,950

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

	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 435,740	$ 273,170
Working capital	$ 405,217	$ 232,603
Total assets	$ 476,111	$ 313,437
Total liabilities	$ 53,777	$ 55,635
Total stockholders' equity	$ 422,334	$ 257,802

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