Cogent Biosciences Reports First Quarter 2025 Financial Results

May 6, 2025

Three Registration-Directed Top-line Data Readouts Remain on Track in 2025:

SUMMIT in NonAdvanced SM expected in July, APEX in Advanced SM expected in second half of the-year and PEAK in GIST expected by end of year

Ended 1Q 2025 with $245.7 million in cash, sufficient to fund operations into late 2026

WALTHAM, Mass. and BOULDER, Colo., May 06, 2025 (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, 2025.

“The first quarter of 2025 was very productive for Cogent as our team focused on executing across our portfolio in preparation for three transformative data readouts this year. We look forward to reporting top-line results from our registration-directed SUMMIT trial with bezuclastinib in patients with nonadvanced systemic mastocytosis in July, followed later in the year with top-line results from our APEX and PEAK trials,” said Andrew Robbins, the Company’s President and Chief Executive Officer. “While we are preparing for a potential launch of bezuclastinib in 2026, we are also very proud of the progress we have made with our early-stage pipeline, including presentations from four distinct programs recently at the annual AACR conference.”

Recent Business Highlights

- Announced expanded clinical results from the Open Label Extension (OLE) portion of the Company’s ongoing SUMMIT trial evaluating bezuclastinib in patients with nonadvanced systemic mastocytosis (NonAdvSM) at the 2025 American Academy of Allergy Asthma & Immunology Annual Meeting (AAAAI) meeting.
  - Bezuclastinib showed a 65% mean improvement in Total Symptom Score (TSS) at 48 weeks, including 88% of patients achieving at least a 50% reduction in TSS.
  - The safety profile for bezuclastinib remains favorable, with adverse events reported primarily as low-grade and reversible. No treatment-related bleeding or cognitive impairment was observed. The most common treatment-related adverse events were hair discoloration and transient elevations in liver transaminases. All cases of elevated transaminases were asymptomatic and fully reversible.
- Presented updated preclinical data from the company’s KRAS, PI3Kα, FGFR2/3 and ErbB2 candidates at the American Association of Cancer Research (AACR) annual meeting.

Upcoming Milestones

- Announce top-line results from SUMMIT in July 2025. SUMMIT is a registration-directed, randomized, double-blind, placebo-controlled, global, multicenter, clinical trial of bezuclastinib in patients with NonAdvSM.
- Announce top-line results from APEX in the second half of 2025. APEX is a registration-directed, global, open-label trial in patients with advanced systemic mastocytosis (AdvSM).
- Announce top-line results from PEAK by the end of 2025. PEAK is a global, blinded, randomized Phase 3 clinical trial studying the combination of bezuclastinib and sunitinib versus sunitinib alone in patients with imatinib-resistant gastrointestinal stromal tumors (GIST).

First Quarter 2025 Financial Results

Cash and Cash Equivalents: As of March 31, 2025, cash, cash equivalents and marketable securities were $245.7 million. During the quarter, the Company sold shares under the Company’s at-the-market (ATM) stock offering for net proceeds of $24.3 million and incurred a non-recurring payment of $9.6 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 late 2026, including through clinical readouts from ongoing SUMMIT, PEAK, and APEX registration-directed trials.

R&D Expenses: Research and development expenses were $63.0 million for the first quarter of 2025 compared to $52.7 million for the first quarter of 2024. The increase was primarily due to costs incurred to support our on-going SUMMIT, PEAK and APEX clinical trials and to the continued progression of our early stage, preclinical and discovery programs. R&D expenses include non-cash stock compensation expense of $5.3 million for the first quarter of 2025 as compared to $4.4 million for the first quarter of 2024.

G&A Expenses: General and administrative expenses were $11.9 million for the first quarter of 2025 compared to $9.7 million for the first quarter of 2024. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $4.8 million for the first quarter of 2025 as compared to $5.0 million for the first quarter of 2024.

Net Loss: Net loss was $72.0 million for the first quarter of 2025 compared to a net loss of $58.3 million for the first quarter of 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. The company also has an ongoing Phase 1 study of its novel internally discovered FGFR2 inhibitor. In addition, the Cogent Research Team is developing a portfolio of novel targeted therapies to help patients fighting serious, genetically driven diseases targeting mutations in ErbB2, PI3Kα and KRAS. 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 expectation to report SUMMIT top-line results in July 2025; the expectation to report APEX top-line results in the second half of 2025; the expectation to report PEAK top-line results by the end of 2025; the company's anticipated cash runway into late 2026; and the potential commercial launch of bezuclastinib in 2026. 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)
(unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 63,029	$ 52,705
General and administrative	11,904	9,699
Total operating expenses	74,933	62,404
Loss from operations	(74,933)	(62,404)
Other income:		
Interest income	2,952	4,057
Other expense, net	(5)	(1)
Total other income, net	2,947	4,056
Net loss	$ (71,986)	$ (58,348)

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

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 245,661	$ 287,077
Working capital	$ 203,556	$ 240,762
Total assets	$ 283,798	$ 327,898
Total liabilities	$ 64,803	$ 71,612
Total stockholders' equity	$ 218,995	$ 256,286

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