# Cogent Biosciences Reports Recent Business Highlights and Second Quarter 2025 Financial Results

August 5, 2025

*Reported positive top-line results from SUMMIT evaluating bezuclastinib in patients with NonAdvanced Systemic Mastocytosis, achieving statistical significance across all primary and key secondary endpoints*

*On track to share pivotal trial results from PEAK in GIST and APEX in AdvSM in 2H 2025*

*$453 million in pro-forma cash sufficient to fund operations through anticipated launch and into 2027; includes proceeds from upsized $230 million public offering in July 2025*

WALTHAM, Mass. and BOULDER, Colo., Aug. 05, 2025 (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 second quarter ended June 30, 2025.

"We were thrilled to announce bezuclastinib's impressive performance in the SUMMIT trial, demonstrating clinically meaningful and statistically significant results across all primary and key secondary endpoints," said Andrew Robbins, the Company's President and Chief Executive Officer. "These positive data along with the favorable safety profile give us confidence that bezuclastinib has the potential to become the new standard-of-care for NonAdvSM patients. Supported by our recent upsized public offering, Cogent is advancing our mission from a position of strength as we prepare to report top-line results from two additional pivotal trials in GIST and AdvSM in the second half of this year, submit our first New Drug Application by the end of 2025 and make continued progress toward the anticipated commercial launch of bezuclastinib in 2026."

**Recent Business Highlights**

- Announced positive top-line results from the registration-directed Part 2 of the SUMMIT clinical trial in NonAdvanced Systemic Mastocytosis (NonAdvSM) patients.
    - The SUMMIT trial, which was designed to assess the clinical benefit of bezuclastinib versus placebo, achieved its primary endpoint with a highly statistically significant difference in the mean change in Total Symptom Score (TSS) at 24 weeks (p=0.0002). TSS was assessed by the Mastocytosis Symptom Severity Daily Diary (MS2D2). The bezuclastinib arm had a mean reduction of 24.3 points in TSS at 24 weeks, versus the placebo arm which had a mean reduction of 15.4 points in TSS, resulting in a placebo-adjusted TSS improvement of 8.91 points. In addition, the SUMMIT trial demonstrated highly statistically significant benefit across all key secondary endpoints, including reduction of serum tryptase on which 87.4% of bezuclastinib-treated patients had ≥50% reduction, compared to no patients in the control arm (87.4% vs. 0%; p<0.0001).
    - Bezuclastinib demonstrated a favorable safety and tolerability profile in SUMMIT.
        - The majority of treatment emergent adverse events (TEAEs) (98.3% in bezuclastinib arm vs. 88.3% in placebo arm) were of low grade. The most frequent TEAEs reported on bezuclastinib treatment were hair color change (69.5% bezuclastinib vs. 5.0% placebo), altered taste (23.7% bezuclastinib vs. 0% placebo), nausea (22.0% bezuclastinib vs. 13.3% placebo) and ALT/AST elevations (22.0% bezuclastinib vs. 6.6% placebo; ≥Gr 3, 5.9% vs. 0%). Serious AEs occurred in 4.2% of patients treated with bezuclastinib, compared to 5.0% of patients treated with placebo. Discontinuations due to treatment-related AEs occurred in 5.9% of patients treated with bezuclastinib, all due to ALT/AST elevations and all patients fully resolved. There were no hepatic AEs reported in any patient other than transient and manageable lab abnormalities.
- Announced two financial transactions, positioning Cogent with access to over $800 million in capital.
    - In June, secured a debt financing facility of up to $400 million with SLR Capital Partners. An initial tranche of $50 million was drawn at closing in June 2025, with additional tranches available upon achieving key clinical and commercial milestones.
    - In July, successfully closed an upsized underwritten public offering of 25,555,556 shares of common stock at $9.00 per share, including the full exercise of the underwriters' option to purchase an additional 3,333,333 shares. This offering generated net proceeds of $215.8 million.

**Anticipated Upcoming Milestones**

- Announce top-line results from PEAK in the second half 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).
- 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).
- Submit Cogent's first NDA for bezuclastinib by the end of 2025.

**Second Quarter 2025 Financial Results**

**Cash Position:** As of June 30, 2025, Cogent had cash, cash equivalents and marketable securities of $237.8 million. The company expects its existing cash, cash equivalents and marketable securities, together with the net proceeds from the $230 million upsized public offering in July 2025, will be sufficient to fund its operating expenses and capital expenditure requirements into 2027, including through potential FDA approval of bezuclastinib for NonAdvSM and early commercial launch activities.

**R&D Expenses:** Research and development expenses were $62.2 million for the second quarter of 2025 as compared to $54.3 million for the second 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 $5.0 million for the second quarter of 2025 as compared to $4.7 million for the second quarter of 2024.

**G&A Expenses:** General and administrative expenses were $13.4 million for the second quarter of 2025 as compared to $10.1 million for the second 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 second quarter of 2025 as compared to $5.3 million for the second quarter of 2024.

**Net Loss:** Net loss was $73.5 million for the second quarter of 2025 as compared to a net loss of $59.0 million for the same period of 2024.

**Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)**

Cogent also announced today that, on July 30, 2025, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grants of "inducement" equity awards to six new employees under the company's 2020 Inducement Plan with a grant date of August 4, 2025. The awards were approved in accordance with Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market. The employees received, in the aggregate, nonqualified options to purchase 172,450 shares of Cogent common stock. Each option has a 10-year term, an exercise price equal to the closing price of Cogent's common stock on the grant date, and a four-year vesting schedule with 25% vesting on the one-year anniversary of the grant date and the remainder vesting in equal monthly installments over the subsequent 36 months, provided such employee remains employed through each such vesting date.

**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 FGFR2/3 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 company's expectation to report top-line results from both PEAK and APEX in the second half of 2025; the potential for bezuclastinib to become the new standard of care for NonAdvSM patients; the company's expectation to submit its first NDA by the end of 2025; the anticipated commercial launch of bezuclastinib in 2026; and the company's anticipated cash runway into 2027, including through potential FDA approval of bezuclastinib for NonAdvSM and early commercial launch activities. 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 or 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Operating expenses: | | | | |
| Research and development | $ 62,203 | $ 54,294 | $ 125,232 | $ 106,999 |
| General and administrative | 13,378 | 10,093 | 25,283 | 19,792 |
| Total operating expenses | 75,581 | 64,387 | 150,515 | 126,791 |
| Loss from operations | (75,581) | (64,387) | (150,515) | (126,791) |
| Other income: | | | | |
| Interest income | 2,373 | 5,393 | 5,325 | 9,450 |
| Interest expense | (314) | — | (314) | — |
| Other income (expense), net | (6) | 44 | (11) | 43 |
| Total other income, net | 2,053 | 5,437 | 5,000 | 9,493 |
| Net loss | $ (73,529) | $ (58,950) | $ (145,515) | $ (117,298) |

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

| | June 30, 2025 | December 31, 2024 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 237,848 | $ 287,077 |
| Working capital | $ 186,586 | $ 240,762 |
| Total assets | $ 274,817 | $ 327,898 |
| Total liabilities | $ 119,781 | $ 71,612 |
| Total stockholders' equity | $ 155,036 | $ 256,286 |

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