Cogent Biosciences Reports Recent Business Highlights and Third Quarter 2025 Financial Results

November 3, 2025

Phase 3 PEAK results in 2nd-line GIST patients expected in November; pivotal APEX results in AdvSM patients expected in December

Breakthrough Therapy Designation granted for bezuclastinib; New Drug Application (NDA) filing for NonAdvSM remains on track for year-end 2025

Multiple bezuclastinib abstracts selected for presentation at the 67th Annual Meeting of the American Society of Hematology (ASH); SUMMIT data in NonAdvSM selected for two oral presentations

Plan to showcase novel JAK2 V617F mutant-selective candidate at ASH 2025

Strong pro forma cash position of $430 million expected to fund operations through anticipated launch of bezuclastinib and into 2027

WALTHAM, Mass. and BOULDER, Colo., Nov. 03, 2025 (GLOBE NEWSWIRE) -- Cogent Biosciences, Inc. (Nasdaq: COGT), a biotechnology company focused on developing precision therapies for genetically defined diseases, today reported recent business highlights and financial results for the third quarter ended September 30, 2025.

“Cogent had a very productive and busy third quarter and we now find ourselves weeks away from reporting top-line results from our Phase 3 PEAK trial of bezuclastinib plus sunitinib in Gastrointestinal Stromal Tumor (GIST) patients and our registration-directed APEX trial in Advanced Systemic Mastocytosis (AdvSM) patients. In addition, we are pleased to announce we will have three bezuclastinib presentations at ASH 2025, including two oral presentations focused on the results from the SUMMIT trial in NonAdvanced Systemic Mastocytosis (NonAdvSM) patients,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “On top of this progress, we recently presented updated preclinical data from our research pipeline that demonstrated potential best-in-class attributes of our pan-KRAS inhibitor and plan to describe for the first time at ASH 2025 our highly potent, highly selective JAK2 V617F mutant-selective inhibitor. Both of these programs are on track for IND in 2026. Our continued financial discipline and business execution position us well as we head into pivotal data readouts and prepare for our first NDA filing for NonAdvSM later this year.”

Recent Business Highlights

- Announced alignment with the U.S. Food and Drug Administration (FDA) on the SUMMIT New Drug Application (NDA) submission plan for broad NonAdvSM patient population following a productive pre-NDA meeting, as well as the receipt of Breakthrough Therapy Designation for bezuclastinib in NonAdvSM patients previously treated with avapritinib and in patients with Smoldering Systemic Mastocytosis; populations with no currently approved standard of care.
- Reported positive top-line results from SUMMIT evaluating bezuclastinib in patients with NonAdvSM, achieving statistical significance across all primary and key secondary endpoints.
- Announced multiple presentations have been accepted at the 67th Annual Meeting of the American Society of Hematology (ASH) being held December 6-9, 2025, in Orlando, FL, including two SUMMIT oral presentations and a poster presentation on Cogent’s novel JAK2 V617F mutant-selective inhibitor, the company’s newest discovery stage program. Details of the ASH presentations can be found in a separate release issued today.
- Recently received clearance from the FDA on Cogent’s Investigational New Drug (IND) submission for CGT4255, a novel, selective, potent, CNS-penetrant ErbB2 inhibitor. A Phase 1 dose escalation trial is on track to initiate in November.
- 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. Cogent also recently raised $39 million through targeted share sales via the Company’s at-the-market facility (ATM).

Anticipated Upcoming Milestones

- Announce top-line results from PEAK in November 2025. PEAK is a global, randomized Phase 3 clinical trial studying the combination of bezuclastinib and sunitinib versus sunitinib alone in patients with imatinib-resistant GIST.
- Announce top-line results from APEX in December 2025. APEX is a registration-directed, global, open-label trial in patients with AdvSM.

- Submit Cogent's first NDA for bezuclastinib by the end of 2025.

Third Quarter 2025 Financial Results

Cash Position: As of September 30, 2025, cash, cash equivalents and marketable securities were $390.9 million, as compared to $345.5 million as of June 30, 2025. The company believes that its cash, cash equivalents and marketable securities, together with the $39.0 million gross proceeds from shares sold through the ATM since last quarterly filing, 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 $69.0 million for the third quarter of 2025 as compared to $63.6 million for the third 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 $5.4 million for the third quarter of 2025 compared to $4.8 million for the third quarter of 2024.

G&A Expenses: General and administrative expenses were $14.4 million for the third quarter of 2025 as compared to $11.8 million for the third quarter of 2024. The increase was primarily due to the growth of the organization. G&A expenses include non-cash stock compensation expense of $5.2 million for the third quarter of 2025 compared to $5.6 million for the third quarter of 2024.

Net Loss: Net loss was $80.9 million for the third quarter of 2025 as compared to a net loss of $70.6 million for the same period of 2024.

Inducement Grants Under Nasdaq Listing Rule 5635(c)(4)
Cogent also announced today that on October 22, 2025, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grant of "inducement" equity awards to five new employees under the company's 2020 Inducement Plan with a grant date of November 3, 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 89,500 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. 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 FGFR2/3, ErbB2, PI3Kα, KRAS and JAK2. 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: plans to present top-line results from the company's PEAK trial in November 2025; plans to present top-line results from the company's APEX trial in December 2025; the company's plans to file an NDA for NonAdvSM before the end of 2025; expectations that the company's cash is sufficient to fund operations through anticipated commercial launch and into 2027; the best-in-class potential of the company's pan-KRAS inhibitor; the company's plans to file INDs in 2026 for both of its KRAS and JAK2 programs; the company's expectation that bezuclastinib will be approved by the FDA for commercial use for patients with NonAdvSM; and the company's plans to initiate a Phase 1 trial for its ErbB2 program before the end of 2025. 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. 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 a 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 68,989	$ 63,614	$ 194,221	$ 170,613
General and administrative	14,366	11,800	39,649	31,592
Total operating expenses	83,355	75,414	233,870	202,205
Loss from operations	(83,355)	(75,414)	(233,870)	(202,205)
Other income:				
Interest income	3,887	4,779	9,212	14,229
Interest expense	(1,459)	—	(1,773)	—
Other income (expense), net	(3)	1	(14)	44
Total other income, net	2,425	4,780	7,425	14,273
Net loss	$ (80,930)	$ (70,634)	$ (226,445)	$ (187,932)

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

	September 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 390,890	$ 287,077
Working capital	$ 334,998	$ 240,762
Total assets	$ 425,933	$ 327,898
Total liabilities	$ 123,469	$ 71,612
Total stockholders' equity	$ 302,464	$ 256,286

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