Cogent Biosciences Reports Recent Business Highlights and Fourth Quarter and Full Year 2025 Financial Results

February 17, 2026

- *SUMMIT NDA for bezuclastinib in patients with NonAdvSM submitted in December 2025; APEX NDA submission for bezuclastinib in patients with AdvSM on track for 1H 2026*
- *PEAK NDA initiated for bezuclastinib in patients with 2L GIST under Real-Time Oncology Review (RTOR) and Breakthrough Therapy Designation (BTD); completion of NDA on track for April 2026*
- *Six abstracts from SUMMIT trial of bezuclastinib in patients with NonAdvSM accepted for presentation at 2026 AAAAI annual meeting*
- *Strong financial position with $901 million sufficient to fund operations into 2028*

WALTHAM, Mass. and BOULDER, Colo., Feb. 17, 2026 (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 reported financial results for the fourth quarter and full year of 2025.

“Following three positive pivotal trials in 2025, we have entered 2026 with tremendous momentum and multiple value-creating regulatory catalysts underway,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “We have submitted our SUMMIT NDA for bezuclastinib in patients with NonAdvSM, initiated our PEAK NDA under the FDA’s RTOR program for bezuclastinib in patients with second-line GIST, and remain on track to submit our APEX NDA for bezuclastinib in patients with AdvSM in the first half of this year. These recent and upcoming milestones underscore the breadth of bezuclastinib’s best-in-class potential across KIT-mutant driven diseases. With a very strong balance sheet entering 2026, we will soon finish building our commercial organization and will be ready to launch bezuclastinib in the second half of 2026.”

Recent Company Highlights

- In February 2026, announced that six abstracts from the SUMMIT trial of bezuclastinib in patients with NonAdvanced Systemic Mastocytosis (NonAdvSM) have been accepted for presentation at the 2026 AAAAI annual meeting.
- In January 2026, announced that the U. S. Food and Drug Administration (FDA) agreed to accept the PEAK NDA for bezuclastinib in patients with Gastrointestinal Stromal Tumors (GIST) who have received prior treatment with imatinib under the Real-Time Oncology Review (RTOR) program. Shortly thereafter Cogent initiated the NDA submission to the FDA under this program. Based on the results from the PEAK trial, in January 2026 bezuclastinib was also granted Breakthrough Therapy Designation for this patient population.
- In December 2025, presented full data from the SUMMIT trial evaluating bezuclastinib in patients with NonAdvSM, at the American Society of Hematology (ASH) annual meeting, and submitted an NDA for bezuclastinib in NonAdvSM, supported by the SUMMIT dataset. Key findings from SUMMIT included:
  - Clear clinical benefit across all symptom domains, including significant improvements across 11 individual symptoms and the most severe symptom at baseline
  - Reduction in objective measures of disease, including serum tryptase, correlating with improvements in symptom severity, representing the first demonstration of this relationship in NonAdvSM patients
  - Forty-eight-week data showing continued deepening of symptomatic improvement over time
- In December 2025, announced topline results from the APEX trial evaluating bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM), APEX is a registration-directed, global, open-label trial evaluating bezuclastinib in patients with AdvSM. Key findings included:
  - Rapid and deep clinical benefit, with an objective response rate (CR+CRh+PR+CI) of 57% per mIWG criteria and 80% per PPR criteria
  - A powerful effect on mast cell burden, with 89% of patients achieving a ≥50% reduction in bone marrow mast cells or clearance of aggregates
- In December 2025, announced initial preclinical results from the company’s novel, potent, selective JAK2 V617F inhibitor CGT1145 at the ASH annual meeting. These results showcased greater than 100-fold selectivity for JAK2 V617F mutations over JAK2 WT inhibition, positioning CGT1145 with a potential best-in-class profile.
- In November 2025, successfully completed concurrent public offerings of common stock and convertible senior notes for net proceeds of approximately $546.8 million.
- In November 2025, announced topline results from the Phase 3 PEAK trial of bezuclastinib in combination with sunitinib for patients with GIST who have received prior treatment with imatinib, becoming the first positive Phase 3 trial in second-line GIST patients in over 20 years. Highlights include:

    - 16.5 months median progression free survival (mPFS) for bezuclastinib plus sunitinib compared to 9.2 months mPFS for sunitinib monotherapy (HR=0.50, CI: 0.39-0.65; p<0.0001)
    - 46% Objective Response Rate (ORR) reported for bezuclastinib combination compared to 26% ORR for sunitinib monotherapy (p<0.0001)
    - The safety profile of the bezuclastinib combination was well tolerated with no unique risks observed with the combination when compared to the known safety profile of sunitinib
- In October 2025, shared progress on Cogent's internally developed KRAS(ON/OFF) inhibitor CGT1263 in a poster at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Updated results demonstrated clear selectivity over HRAS and NRAS, with picomolar (pM) activity across a broad panel of KRAS mutant cell lines. In addition, the poster also characterized CGT1815 (the prodrug of CGT1263), which is designed to optimize human pharmacokinetic performance, supported by pharmacokinetics data from both CGT1815 and CGT1263 across multiple species. Finally, the poster highlighted outcompete data in $KRAS^{G12D}$ and $KRAS^{G12V}$ tumor growth inhibition studies when compared to other KRAS exemplars including RMC-6236.

Projected Near-Term Milestones

Bezuclastinib

- Acceptance of the NDA for bezuclastinib in NonAdvSM in February 2026
- Complete submission of PEAK NDA in April 2026 for bezuclastinib in patients with GIST who have received prior treatment with imatinib
- Submit APEX NDA in 1H 2026 for bezuclastinib in patients with AdvSM
- Present detailed clinical data from the PEAK and APEX pivotal trials at major medical meetings during 1H 2026
- Present updated SUMMIT data across six poster presentations at the AAAAI Annual meeting in February 2026
- Pending FDA approval, launch bezuclastinib in the second half of 2026

Pipeline

- Submit Investigational New Drug (IND) applications for CGT1815, Cogent's novel, selective pan-KRAS(ON) inhibitor and CGT1145, Cogent's novel, selective JAK2 V617F inhibitor
- Share clinical data on CGT4859, Cogent's selective and potent FGFR 2/3 inhibitor, from its Phase 1/2 study in patients with alterations in FGFR2 or FGFR3
- Complete dose escalation for both CGT4255, Cogent's CNS-penetrant, selective mutant ErbB2 inhibitor, and CGT6297, Cogent's novel, selective PI3Kα inhibitor

Bezuclastinib - Expanded Access Program

Working with the FDA, Cogent has established active Expanded Access Programs (EAPs) for U.S. patients with GIST or SM who meet disease-specific criteria and could benefit from treatment with bezuclastinib or the combination of bezuclastinib and sunitinib. A growing number of sites now offer access to the bezuclastinib EAPs. For more information please visit: https://www.cogentbio.com/bezuclastinib-program-development/#our-expanded-access-policy

Upcoming Investor Conference

- Leerink Healthcare Conference on Wednesday, March 11 at 10:40 a.m. ET.
    - A live webcast can be accessed on the Investors & Media page of Cogent's website at investors.cogentbio.com/events. A replay will be available approximately two hours after completion of the event and will be archived for up to 30 days.

Fourth Quarter and Full Year 2025 Financial Results

Cash and Cash Equivalents: As of December 31, 2025, Cogent had cash, cash equivalents and marketable securities of $900.8 million. Fourth quarter cash usage was driven largely by non-recurring items, including the repayment of $54.8 million of long-term debt and approximately $38.5 million of one-time, performance-based equity compensation.

R&D Expenses: Research and development expenses were $75.6 million for the fourth quarter of 2025 and $269.8 million for the year ended December 31, 2025, as compared to $62.0 million for the fourth quarter of 2024 and $232.7 million for the year ended December 31, 2024. The change was driven by the continued development of bezuclastinib across three pivotal trials, including costs associated with the completed and planned NDA filings, as well as the continued progression of our early stage, preclinical and discovery programs. R&D expenses include non-cash stock compensation expense of $7.5 million for the fourth quarter of 2025 and $23.1 million for the year ended December 31, 2025, as compared to $5.0 million for the fourth quarter of 2024 and $19.0 million for the year ended December 31, 2024.

G&A Expenses: General and administrative expenses were $23.9 million for the fourth quarter of 2025 and $63.6 million for the year ended December 31, 2025, as compared to $11.7 million for the fourth quarter of 2024 and $43.3 million for the year ended December 31, 2024. The increase was primarily due to the growth of the organization and activities related to the anticipated commercial launch of bezuclastinib. G&A expenses include non-cash stock compensation expense of $8.3 million for the fourth

quarter of 2025 and $23.0 million for the year ended December 31, 2025, as compared to $5.0 million for the fourth quarter of 2024 and $20.8 million for the year ended December 31, 2024.

Net Loss: Net loss was $102.5 million for the fourth quarter of 2025 and $328.9 million for the year ended December 31, 2025, as compared to a net loss of $67.9 million for the fourth quarter of 2024 and $255.9 million for the year ended December 31, 2024.

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

Cogent also announced today that, on February 11, 2026, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grants of "inducement" equity awards to twelve new employees under the company's 2020 Inducement Plan with grant dates of February 11, 2026 and February 16, 2026. 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, (i) nonqualified options to purchase 59,300 shares of Cogent common stock and (ii) 47,000 restricted stock units (RSUs). 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 4-year vesting schedule with 25% vesting on the 1-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. The RSUs vest annually in equal installments over 4 years from the grant date, 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 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, 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 submit an NDA for bezuclastinib in patients with AdvSM in the first half of 2026; plans to complete the submission of an NDA for bezuclastinib in combination with sunitinib in patients with GIST in April 2026; the anticipated cash runway into 2028; bezuclastinib's best-in-class potential across KIT-mutant driven diseases; plans to finish building a commercial organization and to launch bezuclastinib in the second half of 2026; the potential best-in-class profile of the company's JAK2 V617F inhibitor; the expectation for FDA to accept the company's NDA for bezuclastinib in NonAdvSM in February 2026; plans to present additional clinical data from the PEAK and APEX trials at major medical meetings during the first half of 2026; and plans to submit INDs and present data on the company's pre-clinical and early clinical stage candidates. 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 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 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 the date hereof.

COGENT BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 75,559	$ 62,045	$ 269,780	$ 232,658

General and administrative	23,934	11,689	63,583	43,281
Total operating expenses	99,493	73,734	333,363	275,939
Loss from operations	(99,493)	(73,734)	(333,363)	(275,939)
Other income:				
Interest income	5,477	3,859	14,689	18,088
Interest expense	(1,289)	—	(3,062)	—
Loss on debt extinguishment	(7,181)	—	(7,181)	—
Other income (expense), net	(6)	1,948	(20)	1,992
Total other income, net	(2,999)	5,807	4,426	20,080
Net loss	$ (102,492)	$ (67,927)	$ (328,937)	$ (255,859)

COGENT BIOSCIENCES, INC.
SELECTED CONSOLIDATEDBALANCE SHEET DATA
(in thousands)
(unaudited)

	December 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	$ 900,765	$ 287,077
Working capital	$ 846,402	$ 240,762
Total assets	$ 937,607	$ 327,898
Total liabilities	$ 301,236	$ 71,612
Total stockholders' equity	$ 636,371	$ 256,286

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