Cogent Biosciences Reports Recent Business Highlights and Third Quarter 2026 Financial Results

November 5, 2026

Preparing for anticipated bezuclastinib launch in GIST; PDUFA action date November 30, 2026

NonAdvSM PDUFA target action date December 30, 2026; AdvSM PDUFA target action date June 29, 2027

Cash balance of $791.1 million expected to fund operations into late 2028

WALTHAM, Mass. and BOULDER, Colo., Nov. 05, 2026 (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, 2026.

"With our commercial team in place, we are prepared to execute on the anticipated launch of bezuclastinib in GIST," said Andrew Robbins, Cogent's President and Chief Executive Officer. "In parallel, our team is preparing for potential approvals in NonAdvanced and Advanced Systemic Mastocytosis and we expect to file INDs for our JAK2 and KRAS pipeline programs this quarter. Backed by a strong balance sheet and a world-class team, we are well positioned to continue our vision of creating best-in-class therapies for patients fighting rare, mutationally driven diseases."

Business Highlights

- Plan to present multiple posters featuring bezuclastinib at the 68th Annual Meeting of the American Society of Hematology (ASH) being held December 12-15, 2026, in New Orleans. Featured results will highlight more detailed analyses from the SUMMIT trial of bezuclastinib's effects on skin and neurocognitive symptoms, longer term pathobiology follow-up and an MS2D2 symptomatic comparison of symptom burden in NonAdvanced Systemic Mastocytosis (NonAdvSM) patients before and after bezuclastinib treatment with that of the general population. Included in these presentations will be the first look at clinical results from the SUMMIT sub-study, investigating the patient benefit of switching from avapritinib to bezuclastinib.
- Announced the initiation of a single-arm, 40 patient extension cohort of the PEAK trial investigating the safety and efficacy of bezuclastinib in combination with sunitinib in first-line GIST patients. This cohort is designed to prospectively measure ORR and PFS in patients with either exon 9 or exon 11 primary mutations.
- Announced the U.S. Food and Drug Administration (FDA) acceptance of the New Drug Application (NDA) for bezuclastinib in Advanced Systemic Mastocytosis (AdvSM).

Anticipated Upcoming Milestones

- Potential FDA approval of bezuclastinib in GIST – PDUFA date of November 30, 2026
- Potential FDA approval of bezuclastinib in NonAdvSM – PDUFA date of December 30, 2026
- Potential FDA approval of bezuclastinib in AdvSM – PDUFA date of June 29, 2027
- Investigational New Drug (IND) applications to be submitted for CGT1815, Cogent's novel, selective pan-KRAS(ON) inhibitor, and CGT1145, Cogent's novel, selective JAK2 V617F inhibitor in Q4 2026
- Complete dose escalation for CGT4255, Cogent's CNS-penetrant, selective mutant ErbB2 inhibitor

Upcoming Investor Conferences

- Guggenheim Healthcare Innovation Conference on November 10 at 7:30 am ET
- UBS Global Biopharma Conference on November 17 at 12:00 pm GMT (7:00 am ET)
- Jefferies Global Healthcare Conference on November 17 at 5:00 pm GMT (12:00 pm ET)
- Piper Sandler Healthcare Conference on December 1 at 11:00 am ET

The live webcasts 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 each event and will be archived for up to 30 days.

Third Quarter 2026 Financial Results

Cash Position: As of September 30, 2026, cash, cash equivalents and marketable securities were $791.1 million, as compared to $792.3 million as of June 30, 2026. The company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements into late 2028, well past all three pending PDUFA action dates for bezuclastinib.

R&D Expenses: Research and development expenses were $75.1 million for the third quarter of 2026 as compared to $69.0 million for the third quarter of 2025. 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 $7.5million for the third quarter of 2026 compared to $5.4 million for the third quarter of 2025.

G&A Expenses: General and administrative expenses were $42.1 million for the third quarter of 2026 as compared to $14.4 million for the third quarter of 2025. The increase was primarily due to continued investments in commercial readiness, including personnel and infrastructure to support the potential launch of bezuclastinib, as well as overall organizational growth. G&A expenses include non-cash stock compensation expense of $9.4 million for the third quarter of 2026 compared to $5.2 million for the third quarter of 2025.

Net Loss: Net loss was $111.4 million for the third quarter of 2026 as compared to a net loss of $80.9 million for the same period of 2025.

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, 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: potential FDA approval and commercial launch of bezuclastinib in GIST; potential FDA approval of bezuclastinib in both NonAdvSM and AdvSM; cash runway expected to fund operations into late 2028 and well past all three pending PDUFA action dates for bezuclastinib; plans to submit INDs for the company's JAK2 and KRAS pipeline programs and to move into clinical development soon; plans to complete dose escalation for CGT4255; and plans to present multiple poster presentations featuring bezuclastinib at ASH 2026 and the contents of those presentations. 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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 75,099	$ 68,989	$ 221,275	$ 194,221

General and administrative	42,085	14,366	102,154	39,649
Total operating expenses	117,184	83,355	323,429	233,870
Loss from operations	(117,184)	(83,355)	(323,429)	(233,870)
Other income:				
Interest income	7,052	3,887	22,121	9,212
Interest expense	(1,243)	(1,459)	(3,673)	(1,773)
Other expense, net	(51)	(3)	(202)	(14)
Total other income, net	5,758	2,425	18,246	7,425
Net loss	$ (111,426)	$ (80,930)	$ (305,183)	$ (226,445)

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

	September 30, 2026	December 31, 2025
Cash, cash equivalents and marketable securities	$ 791,134	$ 900,765
Working capital	$ 730,466	$ 846,402
Total assets	$ 832,142	$ 937,607
Total liabilities	$ 315,884	$ 301,236
Total stockholders' equity	$ 516,258	$ 636,371

Contact: Christi Waarich Senior Director, Investor Relations christi.waarich@cogentbio.com 617-830-1653