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

May 5, 2026

- Planning for dual launches of bezuclastinib in Systemic Mastocytosis and Gastrointestinal Stromal Tumors (GIST)

- Pivotal data from Phase 3 PEAK trial in GIST patients selected for oral presentation at 2026 ASCO annual meeting

- Ended 1Q 2026 with $866.4 million in cash, sufficient to fund operations into 2028

WALTHAM, Mass. and BOULDER, Colo., May 05, 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 announced financial results for the first quarter ended March 31, 2026.

“2026 is shaping up to be a pivotal year for Cogent,” said Andrew Robbins, Cogent’s President and Chief Executive Officer. “We have two NDAs for bezuclastinib under FDA review and expect to submit a third in the first half of this year. These milestones highlight the breadth of bezuclastinib’s potential across GIST and KIT-driven diseases. With a strong balance sheet, we are focused on completing our commercial build and preparing for multiple potential launches.”

Recent Business Highlights

- Announced details for an oral presentation on May 30 at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting featuring pivotal data from the Phase 3 PEAK trial in patients with Gastrointestinal Stromal Tumors (GIST) who have received prior treatment with imatinib
- Presented updated preclinical data from the company’s KRAS and ErbB2 candidates at the American Association of Cancer Research (AACR) annual meeting
- Announced submission of the company’s New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for bezuclastinib in patients with GIST who have received prior treatment with imatinib. Based on the positive results from the PEAK trial, the bezuclastinib NDA was submitted under the FDA’s Real-Time Oncology Review (RTOR) program, which is intended to enable a more streamlined review process. Bezuclastinib was also granted Breakthrough Therapy Designation as a treatment for GIST earlier in 2026.
- Announced the FDA accepted its NDA for bezuclastinib in patients with NonAdvanced Systemic Mastocytosis (NonAdvSM) and assigned a Prescription Drug User Fee Act (PDUFA) target action date of December 30, 2026
- Presented six posters with bezuclastinib in patients with NonAdvSM at the 2026 AAAAI annual meeting
- Initiated Phase 1 studies for both CGT4255, a novel, selective, brain-penetrant ErbB2 inhibitor and CGT6297, a novel, selective and potential best-in-class PI3Kα inhibitor

Upcoming Milestones

Bezuclastinib

- Submit the APEX NDA in the first half of 2026 for bezuclastinib in patients with Advanced Systemic Mastocytosis (AdvSM)
- Present detailed clinical data from the Phase 3 PEAK pivotal trial at the 2026 ASCO annual meeting and from the APEX pivotal trial in the first half of 2026
- Initiate a Phase 2 trial in the first half of 2026 investigating the benefit of the bezuclastinib plus sunitinib combination for first-line GIST patients with exon 9 mutations who are naive to, or recently initiated treatment with, imatinib
- Pending FDA approval(s), 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

- Complete dose escalation for CGT4255, Cogent's CNS-penetrant, selective mutant ErbB2 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. For more information please visit: **https://www.cogentbio.com/bezuclastinib-program-development/#our-expanded-access-policy**

Upcoming Investor Conference

- Jefferies Healthcare Conference on June 3 at 11:05 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.

First Quarter 2026 Financial Results

Cash and Cash Equivalents: As of March 31, 2026, cash, cash equivalents and marketable securities were $866.4 million, which includes net proceeds of $45.7 million from shares recently sold under the Company's at-the-market (ATM) stock offering as well as non-recurring payments totaling $18.0 million related to annual performance-based bonus compensation and a milestone payment to Plexxikon. Based on our current plans, we expect our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into 2028, including the commercialization of bezuclastinib in SM and GIST.

R&D Expenses: Research and development expenses were $75.4 million for the first quarter of 2026 compared to $63.0 million for the first quarter of 2025. The increase was driven by increased early-stage, preclinical and discovery programs as we advance our pipeline of programs into Phase 1 clinical trials and IND-enabling studies, and includes one-time costs associated with the wind down of the FGFR clinical program. R&D expenses include non-cash stock compensation expense of $8.9 million for the first quarter of 2026 as compared to $5.3 million for the first quarter of 2025.

G&A Expenses: General and administrative expenses were $28.2 million for the first quarter of 2026 compared to $11.9 million for the first quarter of 2025. 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 $8.0 million for the first quarter of 2026 as compared to $4.8 million for the first quarter of 2025.

Net Loss: Net loss was $97.4 million for the first quarter of 2026 compared to a net loss of $72.0 million for the first quarter of 2025.

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

Cogent also announced today that, on April 29, 2026, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grants of "inducement" equity awards to seven new employees under the company's 2020 Inducement Plan with a grant date of April 29, 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 62,600 shares of Cogent common stock and (ii) 48,600 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. 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: the anticipated commercial launches of bezuclastinib in SM and GIST starting in the second half of 2026; the anticipated cash runway into 2028; the expectation to submit an NDA for bezuclastinib in patients with AdvSM in the first half of 2026; anticipated presentations of clinical data from PEAK and APEX; plans to initiate a Phase 2 trial investigating the benefit of the bezuclastinib plus sunitinib combination for first-line GIST patients with exon 9 mutations who are naive to, or recently initiated treatment with, imatinib; plans to submit INDs for CGT1815, the company's novel, selective pan-KRAS(ON) inhibitor, and CGT1145, the company's novel, selective JAK2 V617F inhibitor; and plans to complete dose escalation studies for CGT4255, Cogent's CNS-penetrant, selective mutant ErbB2 inhibitor. 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,	
	2026	2025
Operating expenses:		
Research and development	$ 75,365	$ 63,029
General and administrative	28,242	11,904
Total operating expenses	103,607	74,933
Loss from operations	(103,607)	(74,933)
Other income:		
Interest income	7,608	2,952
Interest expense	(1,213)	—
Other income (expense), net	(140)	(5)
Total other income, net	6,255	2,947
Net loss	$ (97,352)	$ (71,986)

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

	March 31, 2026	December 31, 2025
Cash, cash equivalents and marketable securities	$ 866,378	$ 900,765
Working capital	$ 819,822	$ 846,402
Total assets	$ 903,006	$ 937,607
Total liabilities	$ 295,313	$ 301,236
Total stockholders' equity	$ 607,693	$ 636,371

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