

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): August 10, 2026

COGENT BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38443
(Commission
File Number)

46-5308248
(I.R.S. Employer
Identification No.)

180 Third Avenue, 4th Floor
Waltham, Massachusetts
(Address of principal executive offices)

02451
(Zip Code)

Registrant's telephone number, including area code (617) 945-5576
275 Wyman Street, 3rd Floor
Waltham, Massachusetts

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 Par Value	COGT	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934. ☐ m

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 10, 2026, Cogent Biosciences, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter ended June 30, 2026. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference in its entirety.

The information in this Item 2.02 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Cogent Biosciences, Inc. on August 10, 2026, furnished herewith.
104	The cover page from the Company’s Current Report on Form 8-K formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 10, 2026

COGENT BIOSCIENCES, INC.

By: /s/ John Green
John Green
Chief Financial Officer



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

On track for potential approval of bezuclastinib for GIST patients (PDUFA November 30) and NonAdvSM patients (PDUFA December 30) later this year; AdvSM New Drug Application submitted to FDA on June 30

Completed onboarding of expert cross-functional Cogent customer-facing team, including all field-based commercial and medical team members

Strong pro forma cash balance of \$865.9 million, sufficient to fund operations into late 2028

WALTHAM, Mass. and BOULDER, Colo., August 10, 2026 – 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, 2026.

“The first half of 2026 has been marked by transformative milestones toward our vision of creating best-in-class therapies for patients fighting rare, mutationally driven diseases as we submitted three New Drug Applications following positive results from each of the bezuclastinib pivotal trials,” said Andrew Robbins, the Company’s President and Chief Executive Officer. “We are excited to welcome the new Cogent customer facing team to the company, and supported by our strong balance sheet, we are well prepared to launch bezuclastinib and advance the standard of care for patients with GIST and Systemic Mastocytosis while continuing to invest in our broader pipeline of precision therapies for genetically defined diseases.”

Recent Business Highlights

Cogent Biosciences Integrated Business Team

- Successfully hired and onboarded all Integrated Business Team members, spanning clinical account managers, patient access navigators and patient educators. Selected for their expertise in commercializing Oncology and Rare Disease products, Cogent now has an exceptional commercial field team in place across the country. Together with our existing medical affairs team, Cogent is well prepared for potential launch with a broad, expert, cross-functional customer-facing organization.
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Bezuclastinib in GIST

- Presented detailed clinical data from the Phase 3 PEAK trial evaluating bezuclastinib in combination with sunitinib vs. sunitinib monotherapy in patients with imatinib-resistant or intolerant Gastrointestinal Stromal Tumors (GIST) at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.
 - o As of the cutoff date, September 30, 2025, the bezuclastinib combination demonstrated a substantial and highly statistically significant clinical benefit on the primary endpoint of PFS, reducing risk of disease progression or death compared to the current standard of care by 50% (hazard ratio of 0.50, 95% CI: 0.39 – 0.65). mPFS, as assessed by blinded independent central review, was 16.5 months for the bezuclastinib combination vs. 9.2 months for sunitinib monotherapy. Additionally, the bezuclastinib combination demonstrated an unprecedented ORR in imatinib-resistant/intolerant patients, with 46% of patients treated with the bezuclastinib combination achieving an objective response compared to 26% of patients treated with sunitinib. Data for overall survival remains immature.
 - o Based on the ongoing patients receiving treatment on the bezuclastinib arm as of March 31, 2026, the mean duration of treatment for the bezuclastinib combination is estimated to be 21.4 months.
 - Announced the initiation of a single-arm, 40 patient extension cohort of the PEAK trial investigating the safety and efficacy of the bezuclastinib combination in first-line GIST patients with KIT exon 9 primary mutations who have received limited or no imatinib treatment. This cohort is designed to prospectively measure ORR and PFS in this patient population, building upon the 25.1 month mPFS reported in a subgroup of 32 patients with detectable exon 9 mutations treated with the bezuclastinib combination in the Phase 3 PEAK trial.
 - Announced FDA acceptance of the New Drug Application (NDA) with priority review for bezuclastinib in combination with sunitinib in patients with GIST who have received prior treatment with imatinib.
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Bezuclastinib in Systemic Mastocytosis

- Announced submission of the NDA for bezuclastinib in Advanced Systemic Mastocytosis (AdvSM).
- Presented detailed data from the pivotal APEX trial at the 2026 European Hematology Association (EHA) Congress.
 - o As of the March 31, 2026 data cutoff, 81 AdvSM patients were treated with 150 mg of bezuclastinib, including 57 patients with SM-AHN, 11 patients with ASM and 13 patients with MCL. The primary endpoint of response per mIWG-MRT-ECNM was assessed on 68 evaluable patients and showed 65% ORR (CR+CRh+PR+CI), including 57% of patients who achieved CR, CRh or PR as best response.
- Announced completion of enrollment in the “avapritinib switch” SUMMIT extension trial with preliminary results expected by end of 2026.
- Presented preclinical data from the novel JAK2 V617F program at EHA.
 - o The poster highlighted CGT1145, a potent inhibitor of the JAK2 V617F mutation with >100x selectivity over JAK2 WT and the JAK1/3 isoforms, along with high oral bioavailability and low clearance across species. CGT1145 has the potential to eradicate JAK2 V617F myeloproliferative neoplasm propagating cells and induce molecular remission with improved hematologic tolerability.

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
- 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

Second Quarter 2026 Financial Results

Cash Position: As of June 30, 2026, Cogent had cash, cash equivalents and marketable securities of \$792.3 million. The company expects its existing cash, cash equivalents and marketable securities, with the \$73.6 million gross proceeds from shares sold through the Company’s at-the-market (ATM) facility after the end of the quarter, will be sufficient to fund its operating expenses and capital expenditure requirements into late 2028, including through potential FDA approvals of bezuclastinib for GIST, NonAdvSM and AdvSM and early commercial launch activities.

R&D Expenses: Research and development expenses were \$70.8 million for the second quarter of 2026 as compared to \$62.2 million for the second quarter of 2025. The increase was primarily driven by costs to support the SUMMIT, PEAK and APEX clinical programs, regulatory activities associated with potential approvals of bezuclastinib, continued investment in the company's early-stage research pipeline, and pre-approval manufacturing costs that will be capitalized following anticipated FDA approval.

R&D expenses include non-cash stock compensation expense of \$8.6 million for the second quarter of 2026 as compared to \$5.0 million for the second quarter of 2025.

G&A Expenses: General and administrative expenses were \$31.8 million for the second quarter of 2026 as compared to \$13.4 million for the second quarter of 2025. The increase was primarily driven by continued investments in commercial readiness, including personnel and infrastructure to support the anticipated launch of bezuclastinib, as well as overall organizational growth.

G&A expenses include non-cash stock compensation expense of \$8.5 million for the second quarter of 2026 as compared to \$4.8 million for the second quarter of 2025.

Net Loss: Net loss was \$96.4 million for the second quarter of 2026 as compared to a net loss of \$73.5 million for the same period of 2025.

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

Cogent also announced today that, on August 4, 2026, the Compensation Committee of Cogent's Board of Directors, made up entirely of independent directors, approved the grants of "inducement" equity awards to 59 new employees under the company's 2020 Inducement Plan with grant dates of August 4, 2026 and August 10, 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 226,700 shares of Cogent common stock and (ii) 189,700 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, PI3K α , 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 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 receive regulatory approval of bezuclastinib later this year for both GIST patients and NonAdvSM patients; the company's anticipated cash runway into late 2028 and the expectation that it will be sufficient to fund operations through anticipated FDA approvals of bezuclastinib for GIST, NonAdvSM and AdvSM and early commercial launch activities; the company's level of preparation to launch bezuclastinib and advance the standard of care for patients with GIST and Systemic Mastocytosis while also continuing to invest in its broader pipeline of precision therapies for genetically defined diseases; the company's expectation that it will present preliminary results from its "avapritinib switch" SUMMIT extension trial by the end of 2026; the potential of CGT1145 to eradicate JAK2 V617F myeloproliferative neoplasm propagating cells and induce molecular remission with improved hematologic tolerability; the company's plans to submit INDs for both CGT1815, its novel, selective pan-KRAS(ON) inhibitor, and CGT1145, its novel, selective JAK2 V617F inhibitor; and the company's plans to complete dose escalation for CGT4255, its 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 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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 70,811	\$ 62,203	\$ 146,176	\$ 125,232
General and administrative	31,827	13,379	60,069	25,283
Total operating expenses	102,638	75,582	206,245	150,515
Loss from operations	(102,638)	(75,582)	(206,245)	(150,515)
Other income:				
Interest income	7,461	2,373	15,069	5,325
Interest expense	(1,217)	(314)	(2,430)	(314)
Other income (expense), net	(11)	(6)	(151)	(11)
Total other income, net	6,233	2,053	12,488	5,000
Net loss	\$ (96,405)	\$ (73,529)	\$ (193,757)	\$ (145,515)

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

	June 30,	December 31,
	2026	2025
Cash, cash equivalents and marketable securities	\$ 792,300	\$ 900,765
Working capital	\$ 745,524	\$ 846,402
Total assets	\$ 834,546	\$ 937,607
Total liabilities	\$ 302,158	\$ 301,236
Total stockholders' equity	\$ 532,388	\$ 636,371

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